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Northwestern University Law Review

Printed in U.S.A.
Vol. 101, No. 2

GETTING PERMISSION

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INTRODUCTION

Institutional Review Boards (“IRBs”) are the instruments of a system of licensing—a system under which scholars, students, and other researchers must get permission to do research on human subjects. Although the system was established as a means of regulating research, it regulates research by licensing speech and the press. It is, in fact, so sweeping a system of licensing speech and the press that it is reminiscent of the seventeenth century, when Galileo Galilei had to submit to licensing and John Milton protested against it.¹ Accordingly, it is necessary to examine the constitutionality of IRB licensing and, more generally, to explore the dangers of licensing speech and the press. The Supreme Court has come to understand such licensing merely as a sort of prior restraint.² Licensing, however, is a distinctly dangerous type of prior restraint, for it requires one to get permission.

This inquiry focuses on the various laws that generally impose IRB licensing on human subjects research—a range of statutes, regulations, and common law doctrines here called “the IRB laws.” At their center is the Common Rule, which sets out a federal model for the licensing.³ Surrounding it are other laws, federal and state, that give the licensing the obligation

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¹ JOHN MILTON, AREOPAGITICA: A SPEECH OF MR. JOHN MILTON FOR THE LIBERTY OF UNLICENSED PRINTING, TO THE PARLIAMENT OF ENGLAND (1644). Galileo sought a license to print for his *Dialogue* in 1630 and was punished by the Inquisition in 1633—in part because he obtained the license without explaining to the licenser that he had earlier been warned not to advocate his ideas. For details, see *infra* note 190.

² See *infra* text accompanying note 22.

³ The Common Rule has been adopted by seventeen federal agencies and departments, and for the sake of convenience, this article cites the Health and Human Services promulgation of the Common Rule at 45 C.F.R. pt. 46 (2005).

of law.⁴ Under this system of laws, universities and other research institutions establish IRBs to review human subjects research, and consequently most teachers and students must get permission from an IRB before they conduct any such research. There are other uses of IRBs—notably, under FDA regulations—but it is the more general use of IRBs to license human subjects research under the IRB laws that requires immediate attention.⁵

The danger of the IRB laws is evident from their practical implications for teachers and students who do human subjects research. Such persons need permission to begin their research; they need permission to continue the research; they need permission to observe, ask questions, talk, or take notes; indeed, they need permission to use data received from other scholars, to analyze much already published data, and to share, disclose, or otherwise publish significant elements of what they learn.⁶ Sometimes they are denied permission altogether. More typically, they are partly denied permission in a process by which IRBs withhold consent unless researchers modify their plans. Although an IRB can thereby require a researcher not to engage in some types of physical contact, it more typically interferes with the researcher's words—for example, by refusing permission unless he agrees not to ask, say, look at, write down, keep records of, disclose, or otherwise publish what the IRB does not want him to ask, say, etc.⁷ In such

⁴ See *infra* Part II.C.

⁵ See *infra* text accompanying note 40.

⁶ For details of how IRBs require individuals to get permission, see *infra* Part II.A and Philip Hamburger, *The New Censorship: Institutional Review Boards*, 2004 SUP. CT. REV. 271, 290–306. The *New Censorship* article argues that the IRB laws unconstitutionally require licensing of speech and the press but that the doctrines of the U.S. Supreme Court have diminished the clarity of the Constitution's obstacles to licensing and thus have emboldened the government to impose IRBs and have left academics and universities without the confidence to resist. *Id.* at 277–81, 351–54. This Article further develops the basic point that the IRB laws unconstitutionally require licensing of speech and the press. Other arguments about the unconstitutionality of the IRB laws are left aside here—as are related federal attempts at licensing of speech and the press, such as the federal coordination of editorial policies at scientific journals and “Privacy Rule,” 45 C.F.R. pts. 160 & 164, promulgated under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 2021–31 (1996).

⁷ For details, see *infra* Part II.A and Hamburger, *supra* note 6, at 301–06. Advocates of IRBs are apt to say that IRBs do not license publication, but the reality of the licensing does not bear this out. Although IRBs focus most of their demands on the informed consent forms, they use their modification of these forms to get researchers to commit to not disclosing what the IRB considers private information, and as IRBs take an astonishingly broad view of what should be private, the IRBs in this way directly bar publication of perfectly ordinary information. See *infra* text following note 71; *infra* Part II.B.3. IRBs also sometimes deny researchers permission to ask questions or to record or disclose the answers, and although this sort of interference is less common than that relating to names and identifying information, the two are inextricably linked, for an IRB will allow more “sensitive” questions if it is confident that the researcher will not learn or at least will not publish the identity of the persons questioned. Thus, if a researcher wants to publish the names of the persons he is interviewing, he will face more severe scrutiny of his questions. For example, if a student wants to interview or survey members of the Ku Klux Klan, the IRB can force the student to choose between censorship of any names and other identifying information and censorship of the other information the student can learn or publish. See *infra* note 70 and accompanying text.

ways, IRBs censor the entire range of observation, inquiry, recording, talking, writing, and publishing protected by the First Amendment, and far from making a single outrageous assault on this Amendment, IRBs modify or censor well over 100,000 research proposals every year in the United States and stifle countless others that get abandoned or never get started. As a result, IRBs bar important avenues of research—even in fields involving techniques no more dangerous than observation, reading, asking questions, and printing.

Although IRBs raise many constitutional questions, the central problem is their licensing of speech and the press. The IRB laws are frequently justified as a means of protecting human subjects, but there are many legal mechanisms that could be used to limit injury to human subjects without running into constitutional obstacles, and it accordingly is all the more remarkable that the federal government responded with a system of licensing speech and the press. This is something the First Amendment once emphatically forbade, and even though the Supreme Court today reduces this prohibition to a mere presumption against prior restraints, the Court at least considers the presumption distinctively heavy.⁸ The licensing therefore is the foremost constitutional issue, and thus notwithstanding that the IRB laws probably collide with First Amendment doctrine on content discrimination, vagueness, and overbreadth, these usual suspects are put aside here in order to concentrate on the more basic problem.⁹

Rather than confine itself to the surface of the Supreme Court doctrine, this constitutional inquiry about licensing under the IRB laws must dig a little deeper, to reach some aspects of licensing that have largely fallen from view—in particular, to observe that licensing laws require one to get permission. It is no longer entirely clear from Supreme Court doctrine that licensing is a distinct problem, and, as already hinted, licensing therefore usually gets subsumed within the more general problem of prior restraints.¹⁰

⁸ The Court has said that “[t]he presumption against prior restraints is heavier—and the degree of protection broader—than that against limits on expression imposed by criminal penalties.” *Southeastern Promotions, Ltd. v. Conrad*, 420 U.S. 546, 558–59 (1975). See also *infra* text accompanying note 29.

⁹ Another relevant doctrine would be the procedural limitations on licensing enunciated in *Maryland v. Freedman*, 380 U.S. 51 (1965).

¹⁰ See, e.g., Thomas I. Emerson, *The Doctrine of Prior Restraint*, 20 LAW & CONTEMP. PROBS. 648 (1955). Vincent Blasi observes that “[t]he Court no longer asks whether a challenged procedure amounts to the equivalent of a licensing system,” but instead inquires about “[p]rior restraint.” Vincent Blasi, *Toward a Theory of Prior Restraint: The Central Linkage*, 66 MINN. L. REV. 11, 12 (1981). The tendency to reduce licensing to a type of prior restraint can also be observed in case books, as when Stone, Seidman, Sunstein, and Tushnet deal with licensing in a brief note entitled *Licensing as Prior Restraint*. GEOFFREY R. STONE, LOUIS M. SEIDMAN, CASS R. SUNSTEIN & MARK V. TUSHNET, CONSTITUTIONAL LAW 1103–06 (4th ed. 2001).

This argument about permission and individual authority resonates with that made by Vincent Blasi about the relationship between the First Amendment and the character required of citizens. Vincent Blasi, *Free Speech and Good Character: From Milton to Brandeis to the Present*, in ETERNALLY VIGILANT: FREE SPEECH IN THE MODERN ERA 61 (Lee C. Bollinger & Geoffrey R. Stone eds., 2002).

Licensing laws, however, stand apart from other restraints because they require individuals to get permission and thereby deprive individuals of their authority, and this has a range of political, social, and individual dangers. The political danger is most obvious—that such laws deprive individuals of their authority in relation to government. By requiring individuals to get permission for their use of language, licensing laws supplant the authority of individuals with that of government in the very mechanism through which individuals form conceptions of themselves as a people and by which they act, both individually and as a people, to authorize and control their government. This political risk is only one of the dangers of having to get permission to speak or print, but it is already enough to suggest the importance of recognizing that licensing requires one to get permission. Once this requirement is understood—especially once its implications for the political authority of individuals is understood—the First Amendment's distinctively strong bar against licensing can begin to make sense.

It may be thought that licensing laws are dangerous only when they focus on political opinion, which would be reassuring with respect to the IRB laws, for they require the licensing of speech and the press merely in the pursuit of scientific knowledge. The First Amendment, however, barred licensing of speech or the press without regard to subject matter and without regard to distinctions between opinion and knowledge. In fact, such licensing is politically dangerous in undermining individual authority not only as to political opinion, but as to all sorts of opinion and knowledge—the clearest illustration being scientific knowledge. Opinion cannot easily be segregated from knowledge, and politics cannot be understood apart from deeper truths, whether in religion, science, or something else, and thus not only when applied to political opinion but also more profoundly, if less immediately, when applied to matters such as scientific knowledge, the licensing of speech or the press inverts the relation of individuals to government. Even beyond this political danger, the licensing of speech or the press as to scientific knowledge is perilous because, in threatening individual authority, it impedes the development of the sort of knowledge that underlies so much of modern society and its blessings. Indeed, such licensing undermines the sense of authority individuals need to make their own judgments about truth, which can matter for reasons that rise above political and social satis-

Blasi, however, defends the extension of the prohibition against licensing to a prohibition against injunctions, thus generalizing from licensing to prior restraint, and therefore although he recognizes the threat to individual authority from the requirement of having to get permission, he does not as sharply distinguish the severity of this danger as he might have. *Id.* at 72–85. Alexander Meiklejohn argues from the authority of the people, but in a self-consciously open-ended way he suggests that:

The Framers could not foresee the specific issues which would arise as their “novel idea” exercised its domination over the governing activities of a rapidly developing nation. . . . In that sense, the Framers did not know what they were doing. And in the same sense . . . we do not know what they were doing, or what we ourselves are now doing.

Alexander Meiklejohn, *The First Amendment Is an Absolute*, 1961 SUP. CT. REV. 245, 264.

factions. The full range of these political, social, and individual dangers of licensing scientific speech or the press were already becoming apparent in the time of Galileo, and they are no less evident in the era of IRBs.

The modern debates as to whether the Supreme Court should develop a constitutional right of research therefore largely miss the point: Rather than need a newfangled right, academics simply need the old-fashioned freedom of speech and the press. Scientific knowledge consists of hypotheses, theories, or general statements, which get formulated and published in dizzying abundance by individuals so that others can test their generalities and find errors, and it will be seen that when the IRB laws require the licensing of research, they candidly require the licensing of attempts to develop this sort of “generalizable knowledge”—the knowledge that can be reduced to generalizations. This imposition of licensing on attempts to develop generalizations, whether spoken or printed, is the licensing of speech and the press, which the First Amendment once flatly forbade.¹¹ What is therefore needed in response to the IRB laws is not the creation of a right of research, but rather a recognition of the freedom from licensing that Galileo lacked and the First Amendment clearly secured.

This study examines the unconstitutionality (in Parts I and II), the justifications (in Parts III and IV), and finally the dangers of scientific licensing (in Part V). *First*, it will be seen that the First Amendment prohibits the licensing of speech or the press—meaning at least the licensing of verbal language, whether spoken or printed, whether as to opinion or knowledge, and regardless of subject matter. It will be seen, moreover, that this prohibition makes sense, for in requiring individuals to get prior permission, such licensing threatens the authority of individuals in their relation to government, which at a minimum has political dangers. *Second*, although the IRB laws regulate research, and although they appear to do so only through conditions on federal research grants, they actually regulate research by directly licensing speech and the press, and they impose this licensing with the obligation of law—thus leaving little room to escape the conclusion that the IRB laws conflict with the First Amendment. *Third*, although IRBs get justified as a means of enforcing a fiduciary duty on researchers as a profession, the IRB laws are particularly dangerous precisely because they impose such a duty on researchers—a duty that even includes imperfect duties. *Fourth*, notwithstanding that IRBs get justified as a means of preventing harms to human subjects, it will be seen that human subjects research is not particularly harmful, and that IRBs clearly cause far more harm to individuals and society than they prevent—all of which leads to concerns that the IRB laws were adopted not so much in response to empirical evidence of harm as in response to popular fears and anxieties about researchers. *Fifth*,

¹¹ As will be seen below, early licensing laws focused on printing rather than just publishing, and therefore the modern emphasis on publishing tends to reduce the freedom of speech and the press. See *infra* text accompanying note 16.

it is necessary to put to rest any lingering thoughts that the IRB licensing is not dangerous because it focuses on scientific knowledge rather than political opinion. It is true that the IRB laws license the use of speech and the press in the pursuit of scientific knowledge, but this is no less dangerous now than it was in the time of Galileo.

In sum, although the unconstitutionality of the IRB laws should be evident enough when one stands on the narrow constitutional point about licensing, it becomes all the more disturbingly clear when one extends one's vision across the landscape of modern life out toward the wide horizons of scientific knowledge. Modern politics, modern society, and the freedom of individuals to make their own judgments about truth, all depend on the authority of individuals in their use of verbal language, spoken and printed, as to all sorts of matters—not least, scientific knowledge—and by licensing the use of speech and the press in the pursuit of such knowledge, the IRB laws threaten the individual authority on which all these political, social, and individual blessings depend. The IRB laws thus illustrate the danger of requiring permission for speech or the press, and they thereby reveal the need to restore the First Amendment's barrier against licensing.

I. LICENSING

Nothing was more severely forbidden by the First Amendment's guarantee of speech and the press than licensing—the requirement that one get permission before speaking or using the press—and this proscription was fortunate.¹² There are many possible threats to the freedom of speech and the press, and the danger from licensing therefore has come to seem less significant than it did in the eighteenth century—even to the point that the Supreme Court tends to allude not to licensing, but rather to a broader range of “prior restraints,” which it subjects to a mere presumption of unconstitutionality. The Court, however, thereby comes close to losing sight of the distinctive character and danger of licensing.¹³ Licensing laws essentially require one to get permission, and this requirement of getting permission makes licensing a particularly serious threat to the authority of individuals in relation to government. Accordingly, although the First Amendment's unequivocal prohibition of licensing has slipped below the surface of Supreme Court doctrine, the old prohibition against licensing remains vitally important, and it needs to be brought back into view.

A. *The First Amendment's Prohibition on Licensing*

The First Amendment's guarantee of speech and the press most centrally prohibited the licensing of speech and the press. First Amendment ideals have expanded beyond such licensing to include other methods and

¹² See *infra* text accompanying note 19.

¹³ See *infra* text accompanying note 26.

objects of restraint, and as a result the once absolute prohibition on licensing of speech and printing has become a mere presumption. Even the notion that licensing is a distinct danger gets lost amid the broader categories of prior and post-publication restraints. Nonetheless, just below modern doctrine one can observe the historical and conceptual core of the freedom of speech and the press, which remains the freedom from licensing speech or the press—a freedom from having to get permission for the use of verbal language, whether spoken or printed—and this still should be considered absolutely forbidden.

Historically, the speech-and-press guarantee of the First Amendment forbade at least the licensing of speech and the press. It provided that “Congress shall make no law . . . abridging the freedom of speech, or of the press.”¹⁴ When the First Amendment was adopted in 1791, the freedom of the *press* was widely understood to include a freedom from the licensing of the press.¹⁵ Although historians tend to assume this was a freedom from the licensing of publication, it was more basically a freedom from the licensing of the press—meaning the licensing of printing—this being the sort of licensing that had prevailed in England and elsewhere in the seventeenth century and that Americans in the eighteenth century most clearly sought to avoid.¹⁶ Although the freedom of the press may have included more, it is not clear from the historical evidence what else it encompassed. Some scholars emphasize potentially broader conceptions of the freedom, but they tend to rely on later evidence, and they do not dispute that the First Amendment was understood at least to include a freedom from licensing.¹⁷ The freedom of *speech* (beyond the context of Parliamentary debate) was less fully elaborated, but the First Amendment evidently was written on the assumption that the freedom enjoyed as to speech was the same as that en-

¹⁴ U.S. CONST. amend. I.

¹⁵ The evidence from the period up through 1791 reveals that the freedom of speech and the press was ordinarily understood as a freedom from licensing. LEONARD LEVY, *THE EMERGENCE OF A FREE PRESS*, chs. VII–VIII (1985). A broader understanding of the freedom of speech and the press only seems to have become more widely accepted during the debates around the Alien and Sedition Acts at the very end of the century. *Id.* at ch. IX. For an early eighteenth-century English claim of freedom of the press from seditious libel prosecutions, see Philip Hamburger, *The Development of the Law of Seditious Libel and the Control of the Press*, 37 STAN. L. REV. 661, 743–44 (1985). For a somewhat similar claim from the 1780s, see LEVY, *supra*, at 209. Scattered early claims of this sort, however, do not displace the evidence assembled by Levy about the more ordinary understanding of the freedom.

¹⁶ That the seventeenth century licensing centrally concerned printing rather than publishing is clear from A DECREE OF STARRE-CHAMBER, CONCERNING PRINTING, sig. B2[r], § II (London, Robert Barker 1637); An Act for Preventing the Frequent Abuses in Printing Seditious Treasonable and Unlicensed Books and Pamphlets and for Regulating of Printing and Printing Presses, 1662, 14 Car. II, c. 33, §2 (Eng.). In contrast, publication—in the sense of sharing a writing with a third party—was a requirement of the law of libel, including the law of seditious libel. Hamburger, *supra* note 15, at 702. For one of many possible illustrations of how the licensing of the press has come to be reduced to a matter of publication, see the quotation from Chief Justice Hughes in the text accompanying *infra* note 21.

¹⁷ See, e.g., JAMES MORTON SMITH, *FREEDOM’S FETTERS: THE ALIEN AND SEDITION LAWS AND AMERICAN CIVIL LIBERTIES* 424–30 (1956).

joyed as to the press, for the Amendment employed the same word “freedom” for each.¹⁸ The sort of speech or the press thus protected from licensing appears to have been at least verbal—in the sense that it was of the sort that could be spoken or read aloud in one language or another. Today, the First Amendment’s guarantee against laws that establish licensing for such speaking or printing may seem extremely narrow, but this was the freedom of speech and the press that the First Amendment most clearly protected in 1791.

On the old assumption that freedom of speech and of the press was a relatively narrow freedom from licensing, the Supreme Court once could speak about the freedom as if it were absolute.¹⁹ William Blackstone and some early American judges generalized about licensing as a “previous restraint,” and, following their usage, Justice Holmes explained the federal and state guarantees of freedom of speech and the press in utterly unqualified terms:

[T]he main purpose of such constitutional provisions is “to prevent all such previous restraints upon publications as had been practiced by other governments,” and they do not prevent the subsequent punishment of such as may be deemed contrary to the public welfare. The preliminary freedom extends as well to the false as to the true; the subsequent punishment may extend as well to the true as to the false.²⁰

In short, other governments had imposed systems of licensing, and far from being subject to government interests, the freedom from this sort of prior restraint extended to false as well as true publications. Even after the Supreme Court expanded the First Amendment freedom of speech and the press, Chief Justice Hughes could still acknowledge the bar against licensing without qualifying it:

The struggle for the freedom of the press was primarily directed against the power of the licensor. It was against that power that John Milton directed his assault by his “Appeal for the Liberty of Unlicensed Printing.” And the liberty

¹⁸ In this sense, the First Amendment’s use of the word “freedom” (like its use of the words “religion” and “thereof”) anticipates a Wittgensteinian observation that the repetition of the word would introduce another word or at least another meaning.

¹⁹ This is obviously not an attempt to revive the position of Justice Hugo Black, who loosely discussed a much broader conception of the freedom of speech and the press as an absolute and who thus confirmed in the minds of many commentators that there are no absolutes in law. For a summary of the debate, see Meiklejohn, *supra* note 10.

²⁰ *Patterson v. Colorado*, 205 U.S. 454, 462 (1907) (citations and emphasis omitted). Incidentally, it should be noted that although Holmes acknowledged much room for subsequent punishments, his words about “the main purpose” did not entirely reject the possibility of constitutional limits on such punishments. Some earlier judges, incidentally, were more precise—as when Chief Justice M’Kean of Pennsylvania said of his state’s constitution that it barred “any attempt to fetter the press by the institution of a *licenser*.” *Respublica v. Oswald*, 1 U.S. (1 Dall.) 319, 325 (Pa. 1788).

of the press became initially a right to publish “without a license what formerly could be published only with one.”²¹

This old freedom appeared absolute.

Gradually, however, the freedom of speech and of press has come to be understood more broadly, and at least on the surface this appears to be entirely an expansion of the liberty protected by the First Amendment. For example, twentieth-century scholars and judges have reconceptualized the freedom from licensing—so that what once was a freedom from having to get permission has become a freedom from prior restraints in general—this being a move that reaches injunctions.²² Even more ambitiously, the scholars and judges have extended the freedom of speech and the press to include a freedom from post-publication restraints.²³ Having thus expanded upon the prohibited method of regulation, they have also broadened the prohibited object of regulation to include not only the verbal language traditionally associated with speech and the press, nor only the full range of communication that can be done by oral and printed means, but also a wide range of other expression, including that done through conduct—such as nude dancing and the burning of flags and crosses.²⁴

Not surprisingly, this expanded definition of the freedom has led to qualifications about access to the freedom. The enlargement of a right can be a mixed blessing, for sometimes “more is less”—this being the dynamic by which a broadened freedom can seem to require diminished access.²⁵

²¹ *Lovell v. City of Griffin*, 303 U.S. 444, 451 (1938) (citation omitted). He added: “While this freedom from previous restraint upon publication cannot be regarded as exhausting the guaranty of liberty, the prevention of that restraint was a leading purpose in the adoption of the constitutional provision.” *Id.* at 451–52 (citation omitted).

²² *Near v. Minnesota*, 283 U.S. 697 (1931); *Hamburger*, *supra* note 6, at 283. This move was probably unnecessary in *Near*, but it would matter in later cases on injunctions in which the underlying laws did not so clearly establish a system of licensing through the courts.

²³ *Near*, 283 U.S. at 283–84.

²⁴ *R.A.V. v. City of St. Paul*, 505 U.S. 377 (1992) (cross burning); *United States v. Eichman*, 496 U.S. 310 (1990) (flag burning); *Texas v. Johnson*, 491 U.S. 397 (1989) (flag burning); *Schad v. Borough of Mount Ephraim*, 452 U.S. 61 (1981) (nude dancing). The Court outlined its test for expressive conduct in *United States v. O'Brien*:

[A] government regulation is sufficiently justified if it is within the constitutional power of the Government; if it furthers an important or substantial governmental interest; if the governmental interest is unrelated to the suppression of free expression; and if the incidental restriction of alleged First Amendment freedoms is no greater than is essential to the furtherance of that interest.

391 U.S. 367, 377 (1968). Such a law must be narrowly tailored, but it does not have to be the least burdensome “imaginable.” *Ward v. Rock Against Racism*, 491 U.S. 781, 797 (1989) (citation omitted).

²⁵ Philip Hamburger, *More Is Less*, 90 VA. L. REV. 835 (2004); see also Vincent Blasi, *The Pathological Perspective and the First Amendment*, 85 COLUM. L. REV. 449, 452–59 (1985); Kenneth L. Karst, *The Freedom of Intimate Association*, 89 YALE L.J. 624, 654 n.140 (1980); William P. Marshall, *Diluting Constitutional Rights: Rethinking ‘Rethinking State Action,’* 80 NW. U. L. REV. 558, 567–68 (1985). The *More Is Less* article observes this dynamic in evolving conceptions of the free exercise of religion. When the Justices expanded their understanding of this right to include a right of exemption from general laws, they introduced qualifications explaining how a sufficiently compelling government

Optimistic generalizations about the extent of a right are popular in an individualistic society such as the United States, but they tend to lead judges to qualify access to the right in terms of a balancing of interests. As valorized in the logic of legal realism, the right is nothing more than an individual interest, which can be outweighed by a sufficiently important government interest—thus reducing constitutional prohibitions to mere presumptions.

In this manner, the expansion of the freedom of speech and the press has led to judicial qualifications. The expanded periphery of the freedom—whether as to prior restraints, post-publication restraints, or various forms of non-verbal expression—has seemed plausible only because it has been accompanied by caveats preserving the interests of government. Although in theory it might have been possible to confine the application of these caveats to the expanded portions of the freedom, the necessity of generalizing about freedom of speech and the press has made it almost inevitable that the caveats would cut into the core—the freedom from licensing. Put simply, to defend the expanded sphere of the freedom, scholars and judges have had to generalize about the freedom as a whole, and they thus have ended up carving out government interests not only from the expanded periphery but also from the historic core. Whereas the Supreme Court once could speak about licensing without qualification, it soon had to explain—as when it expanded the freedom to protect against injunctions—that “the protection even as to previous restraint is not absolutely unlimited.”²⁶ Such qualifications were all the more necessary when the Court extended the freedom to post-publication restraints.²⁷ The Court thus diminished the prohibition against licensing into little more than a presumption that becomes the starting point for a judicial evaluation of government interests. In justification, it sometimes is said in a knowing tone that no right is absolute and that all rights are subject to government interests. Yet this is only true of the freedom of speech and the press because of the expanded definition of the freedom. It may be satisfying to know that the qualifications protecting government interests have made it plausible to expand the freedom at its periphery, but at the same time these qualifications have rendered the once absolute freedom from licensing merely part of a broader freedom that is conditional on the claims of government.

interest could justify “substantial infringement” of the right—thus rendering a previously unqualified right dependent upon the needs of government. *Hamburger, supra*, at 859 (quoting *Sherbert v. Verner*, 374 U.S. 398, 406 (1963)).

Justice Kennedy vigorously protested against this sort of development in the freedom of speech and the press. *Id.* at 888–89 (citing *Simon & Schuster v. Crime Victims Bd.*, 502 U.S. 105, 124–28 (1991) (Kennedy, J., concurring)).

²⁶ *Near*, 283 U.S. at 716. The case could have avoided its conclusion about the conditional character of the freedom by recognizing that the case really concerned licensing in the disguise of an injunction. Instead, however, the Court began to propose a freedom from prior restraints, including not only licensing laws but also injunctions.

²⁷ As the Court explained in *R.A.V.*, “[e]ven the prohibition against content discrimination . . . is not absolute.” 505 U.S. at 387.

Fortunately, the historical and conceptual core of the freedom of speech or the press has not been entirely forgotten. Although the Supreme Court discusses licensing in terms of prior restraint and thus does not acknowledge the distinctive danger of licensing, it at least recognizes that prior restraint is a peculiarly serious problem and that licensing is the paradigmatic example of prior restraint.²⁸ The Court draws upon the historic rejection of licensing to declare forcefully:

The presumption against prior restraints is heavier—and the degree of protection broader—than that against limits on expression imposed by criminal penalties. Behind the distinction is a theory deeply etched in our law: a free society prefers to punish the few who abuse rights of speech *after* they break the law than to throttle them and all others beforehand.²⁹

With licensing as the central exemplar of what is most severely forbidden, the Court concludes that “prior restraints on speech and publication are the most serious and the least tolerable infringement on First Amendment rights.”³⁰

A brief survey of licensing in the United States confirms that although the federal and state governments can adopt a wide variety of licensing laws, the Supreme Court has never heard and rejected the argument here about the constitutional freedom from licensing laws that single out verbal speech or the press. For example, it is true that the states license the practice of medicine, law, and accounting—professions that involve much talking and printing—but they do so because these professionals undertake to act for their clients and thereby assume fiduciary duties. In fulfilling these duties, the professionals act, speak, and exercise judgment on behalf of others, but they are licensed on account of their fiduciary role, not their speech or the press. Of course, a government can make a law that refers to verbal speech and the press when licensing the use of its money or other property, for the freedom of speech and the press was prototypically the sort of right that could be enjoyed in the absence of government, and therefore, unless a government uses its distribution of property to regulate, its failure to subsidize cannot be an abridgment of the freedom of speech or the press. In contrast, the government cannot allude to verbal language when imposing constraints through licensing. Thus, it is dubious whether a law can allude to verbal language when licensing the use of common space or property (such as the airwaves), when licensing the use of public property that has been dedicated to common use (such as the sidewalks or a park), or when distributing funds from a special assessment (such as student fees at a public university). To be sure, a licensing law can specify decibel levels and

²⁸ For example, in *Near*, the Supreme Court argued from the example of “[t]he struggle in England, directed against the legislative power of the licenser,” which “resulted in renunciation of the censorship of the press.” 283 U.S. at 713 (footnote omitted). See also the quotation in note 21.

²⁹ *Southeastern Promotions, Ltd. v. Conrad*, 420 U.S. 546, 558–59 (1975).

³⁰ *Neb. Press Ass’n v. Stuart*, 427 U.S. 539, 559 (1976).

limits on crowding—whether as to common or private property—but it ought not specify verbal language. As it happens, the Supreme Court has allowed licensing of radio broadcasts and demonstrations in ways that include the licensing of verbal language, but the point about verbal language was never raised in such cases, and the Court thus has never directly addressed it.³¹ The Supreme Court, in fact, has only circled around the issue.³² In *Freedman v. Maryland*, for example, the Supreme Court permitted limited licensing of movies, in which pictures and voices were conjoined on a single tape, but this licensing was aimed primarily at the pictures, and it is improbable that the Court would uphold a law requiring licensing of audio tapes, as this would be a law that specified verbal speech as the basis for licensing.³³ Admittedly, the Securities Act of 1933 could be understood as authorizing licensing (for it uses its prohibition on the sale or transportation of securities to obtain SEC licensing of registration statements), but the Supreme Court has not squarely evaluated this, and it seems doubtful that any one such exception should be understood to vitiate the First Amendment's core prohibition against licensing.³⁴

Thus, just below the surface of Supreme Court doctrine, one can discern the remnants of the traditional bar against licensing of speech or the press. The expansion of the freedom of speech and the press has reduced the unequivocal prohibition against licensing to a mere presumption against prior restraints, but the absolute prohibition against licensing remains the intellectual core of the freedom, and as now will be seen, this prohibition against licensing remains of vital importance.

B. *The Threat to the Authority of Individuals in Relation to Government*

Scholars tend to consider licensing an obsolete danger—as if the bar against licensing were an old fashioned restriction, which has become irrelevant in the modern world—and even when scholars try to understand why there might be a particularly severe presumption against licensing, they tend to focus on the dangers of “prior restraints” rather than the dangers of a system requiring one to get permission.³⁵ As a result, the perils of licensing tend to get lost amid the broader but less clear-cut dangers of prior re-

³¹ Of course, the federal licensing of verbal language on the airwaves and the municipal licensing of such language in demonstrations has come to seem constitutionally plausible in part because the Court's doctrines have rendered any post-publication restraint implausible.

³² The federal government's licensing of classified information might be thought to conflict with this conclusion. The licensing laws examined here, however, are regulations rather than conditions on purchases. See *infra* Part II.C.1; see also *Snepp v. United States*, 444 U.S. 507 (1980) (upholding agreement of CIA employee with the agency to get permission before publishing about its activities).

³³ 380 U.S. 51 (1965). For more recent decisions that apply modified versions of *Freedman*'s procedural requirements to the licensing of sexually oriented or adult businesses, see *City of Littleton v. Z.J. Gifts D-4, L.L.C.*, 541 U.S. 774 (2004); *FW/PBS, INC. v. City of Dallas*, 493 U.S. 215 (1990).

³⁴ 15 U.S.C. § 77(e) (2000).

³⁵ See *infra* notes 36–37.

straints. Once licensing is understood, however, not merely as a sort of prior restraint, but as a requirement that one must get permission to speak or print, its dangers become more sharply defined, and the most obvious of these is the political threat: Licensing of speech or the press, considered as a requirement that one get permission, undermines the authority of individuals in relation to government.

At the outset it must be noted that the authority of individuals discussed here is not an authority independent of law or otherwise beyond the duties owed to others. On the contrary, it is an authority ordinarily subject to moral duty and legal regulation, but free from licensing. In the model of society and government assumed by American constitutions, individuals consent to join civil society and submit to civil government, and thus, at least in theory, individual authority and legal obligation are entirely compatible. The consent that reconciles individual authority and legal obligation, however, occurs not once, but repeatedly, whether in elections or continuing submission to government, and it thus depends upon the persistence of individual authority under government and its regulations. Far from a dangerous, extra-legal authority that might be claimed against an ordinary regulation of injury, this continuing authority is merely the basic, residual authority of individuals that can be assumed to remain in them even after the formation of government and its imposition of laws prohibiting injury. Such is the authority threatened by licensing—especially the licensing of speech and the press.

If viewed merely as a type of prior restraint, licensing has obvious dangers, but these have not seemed dramatically greater than the dangers from post-publication restraints. Some scholars, such as Thomas Emerson, emphasize the distinctive dangers of prior restraints, especially licensing:

A system of prior restraint is in many ways more inhibiting than a system of punishment: It is likely to bring under government scrutiny a far wider range of expression; it shuts off communication before it takes place; suppression by a stroke of the pen is more likely to be applied than suppression through a criminal process; the procedures do not require attention to the safeguards of the criminal process; the system allows less opportunity for public appraisal and criticism; the dynamics of the system drive toward excesses, as the history of censorship shows.³⁶

Notwithstanding these concerns, other scholars doubt whether prior restraints should be more strongly prohibited than post-publication restraints. As put by Paul Freund, “it will hardly do to place ‘prior restraint’ in a special category for condemnation,” for even under prior restraints, “the judicial sanction takes its bite” after the fact.³⁷ Thus, when licensing is merely

³⁶ THOMAS I. EMERSON, *THE SYSTEM OF FREEDOM OF EXPRESSION* 506 (1970).

³⁷ Paul A. Freund, *The Supreme Court and Civil Liberties*, 4 VAND. L. REV. 533, 537, 539 (1951). Echoing this complaint about the doctrine of prior restraint, a leading First Amendment casebook observes: “Although the historical origins of the doctrine are clear, its analytical and functional underpin-

considered another sort of prior restraint, its distinctive danger is not apt to stand out, and although prior restraints still are more emphatically barred than post-publication restraints, the difference has become one more of degree than of kind.

Licensing, however, differs from the other sort of prior restraint, injunctions, because it requires individuals to get permission—because it permits rather than prohibits. Most laws protect individuals from harm by prohibiting the harm and allowing either public or private remedies after the fact. Licensing, in contrast, prohibits generally, and then selectively permits what otherwise is forbidden. Thus, prototypically, whereas law prohibits injury, licensing permits what is not injurious, and, by treating conduct as unlawful unless permitted, it reverses the ordinary presumption of liberty—the presumption that, in the absence of a law prohibiting injurious conduct, individuals are free.³⁸

The legal realist will still protest that the penalty for failing to get permission comes after the fact and that therefore a licensing law is really just another post-publication restraint. This, however, ignores the obligation of the law, which requires one to get permission. By focusing on remedies for breach of law rather than the underlying obligation of law, the legal realist gains some insight into judicial reasoning at the risk of entirely missing the obligation of law felt by individuals who must live under it. They experience the law not merely as the physical force inflicted by the judiciary for a breach, but more typically and immediately as the obligation of the rules enacted by the legislature. In this sense, what are misleadingly called “post-publication restraints” are laws that oblige individuals to avoid inflicting injury, and licensing laws are the laws that oblige individuals to get prior permission before doing what is not injurious. Hence, the worry about licensing laws. By imposing an obligation to get permission, such laws deprive individuals of the freedom they are presumed to have in the absence of laws prohibiting injury.

Far from being merely an abstract ideal, this presumption of liberty underlies the very spirit of independence and responsibility that typifies

nings are often puzzling, at best.” GEOFFREY R. STONE ET AL., *THE FIRST AMENDMENT* 125 (2d ed. 2003); see also *Kingsley Books, Inc. v. Brown*, 354 U.S. 436, 441–43 (1957). More generally, a simple notion of prior restraint has come into disrepute. OWEN M. FISS, *THE CIVIL RIGHTS INJUNCTION* 68–74 (1978); Stephen R. Barnett, *The Puzzle of Prior Restraint*, 29 *STAN. L. REV.* 539 (1977); Blasi, *Toward a Theory of Prior Restraint*, *supra* note 10, at 14; John Calvin Jeffries, Jr., *Rethinking Prior Restraint*, 92 *YALE L.J.* 409 (1982); Martin H. Redish, *The Proper Role of the Prior Restraint Doctrine in First Amendment Theory*, 70 *VA. L. REV.* 53 (1984).

³⁸ Of course, this presumption, like any model, is rather stylized—as is the associated notion of injury. Nonetheless, the presumption remains a useful point of reference, which should not be a surprise, for the history of the presumption is a large part of the history of modern law and political theory. According to the theory, individuals enjoy freedom already in the absence of civil government, and they consensually form civil society and government for limited purposes. See, for example, JOHN LOCKE, *TWO TREATISES OF GOVERNMENT* (Peter Laslett ed., Cambridge Univ. Press 1988) (1690), not to mention innumerable early American pamphlets, newspaper articles, and sermons.

Americans, who enjoy a free society not only in governing themselves politically but also in governing themselves under law—in judging for themselves the lawfulness of their actions and how to conduct themselves morally within the bounds of law. This freedom under law, unburdened by any need to get prior permission, is essential to the American experiment in self-governance. In a free society, each individual ordinarily reaches his own conclusions about his conformity to law and morals, and in this sense each individual is, in the first instance, his own judge, having the freedom and the responsibility to decide for himself and at his own risk how the law applies to him and how he should enjoy his freedom within the law.

Licensing, in contrast, leaves individuals in need of permission and thereby inculcates a sense of dependence on government in basic judgments about what conduct is lawful and moral. The government, in effect, treats individuals as too incompetent or corrupt to judge for themselves, and in the course of relieving individuals of the responsibility to make their own decisions about their conformity to law and morality, it divests them of their authority to make such judgments.

By forcing these internal judgments into an external forum, all licensing—not merely that of speech or the press—tends to undermine the capacity of a people to govern themselves, whether personally or politically. America itself is an experiment that relies far more upon the capacity of individual Americans to judge and obey than upon the power of government and its judges to adjudicate and force them. This internal judgment of Americans is part of the self-government by which Americans spare themselves the need for severity from their external judges and government. By judging and restraining themselves, moreover, Americans can internally conform to external demands, whether from government or a higher power, with a sense of their own responsibility—with a sense of self-rule rather than subservience. This internal adjudication and restraint is the most basic self-government, and in the daily exercise of this internal governance, individuals qualify themselves for the responsible exercise of external self-government.

Although the authority of individuals thus can be threatened by licensing in general, it is more seriously threatened by the licensing of speech and the press. Notwithstanding the general danger of licensing, it will be seen that there are circumstances that justify this mode of regulation. By the same token, there is at least one instance in which licensing is so dangerous that it can never be justified: when the law licenses speech or the press. A law imposing this sort of licensing combines a singularly dangerous method with a peculiarly sensitive object, and it therefore was absolutely forbidden.

Such licensing deserves a constitutional barrier because, at the very least, it undermines the relation of individuals to government in matters of speech and the press and thus poses a political danger. In a republican system of government, the authority for government comes from the people and thus ultimately from individuals, but licensing of speech and the press

reverses this relationship, for in requiring individuals to get permission, this licensing suggests that individuals can use language to formulate their knowledge and opinions, including those about government, only with the authority of government. Ordinarily, individuals can judge for themselves what they should say or print, and if they thereby unlawfully injure other individuals or the government, they must pay a penalty afterward for their misuse of their freedom. In contrast, under licensing laws, individuals first must get permission, and in matters of speech and the press, this is apt to impress the people with a sense that their knowledge, ideas, opinions, and arguments depend for their authority upon government, rather than that government depends for its authority upon the knowledge, ideas, opinions, and arguments of the people.

Thus, by requiring individuals to get permission, the licensing of speech or the press dispossesses an independent people of their individual authority and renders them subservient in the very mechanism—language—by which they establish and control their government. Language is the central means by which individuals build up their understandings of themselves and their society—of themselves as human beings and as a people, of their capacity to govern themselves morally and politically, and of their government and the limitations on it. With language, they thus construct their identities, their social relations, their morals, their politics, and their constitutions. Accordingly, for government to require them to get permission before they use language is to turn the entire edifice upside down. One of the distinctive blessings of a society such as the United States is that the centralized authority of government rests on the deeper authority of the people and ultimately the diffused authority of myriad individuals. Licensing of speech or the press most clearly has to be forbidden because it inverts this structure—because it makes individuals dependent on government for the very instrument by which they form themselves as a people and establish and restrain their government.

II. IRB LICENSING

The IRB laws unconstitutionally create a system of licensing speech and the press. These laws purport to impose licensing on “research,” but in fact impose it directly on speech and the press. They do so, moreover, not only through conditions on grants, but also directly by obligation of law. It is therefore difficult to avoid the conclusion that the IRB laws run up against the First Amendment.

This conclusion may initially seem improbable on account of a pair of misunderstandings: that the IRB laws regulate “research” rather than speech or the press, and that they impose IRBs through conditions on research grants rather than the obligation of law.³⁹ The IRB laws, however,

³⁹ For such assumptions, see, for example, *Protecting Human Beings: Institutional Review Boards and Social Science Research*, ACADEME, May–June 2001, at 55, 58–59; John A. Robertson, *The Law of*

candidly regulate research by imposing licensing on speech and the press, and they do so both through conditions and by direct obligation of law. Thus, the usual reassuring assumptions—that IRBs merely concern research and that they only are imposed through conditions on grants—turn out to be distractions from the underlying and utterly unconstitutional realities.

A. *The Structure of the IRB Laws*

Before reaching the constitutional issues, one must observe the structure of the IRB laws. Put simply, the federal government imposes a system of licensing, and research institutions and their IRBs carry it out.

It cannot be overemphasized that the IRB laws under consideration here are those that generally concern human subjects research. There are other laws that rely on IRBs, but they do so for more specialized purposes and therefore are not part of this inquiry. For example, FDA regulations require the use of IRBs, but not for the general regulation of human subjects research.⁴⁰ This distinction will eventually become important when it is observed that the harms from FDA drug trials have nothing to do with the constitutionality of the IRB laws. More immediately, the distinction means that the licensing structure that needs to be understood here is that which focuses on universities and other research institutions, not that which concentrates on the development of new drugs.

Institutional Review Boards, 26 UCLA L. REV. 484, 507, 509 (1979); NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, REPORT AND RECOMMENDATIONS 78–80 (1978) [hereinafter NAT'L COMM'N, REPORT]. The National Commission recognized that “the requirement of prior review and approval by an IRB” might “violat[] constitutional rights of academic freedom and free inquiry,” but it then applied the Court’s weakened doctrines on licensing to conclude that the government may “regulate . . . the methods used in . . . research, in order to protect interests in health, order and safety,” and it observed that the Court’s spending doctrine gave Congress even greater freedom, for “[w]here the IRB system is imposed on researchers as a condition of . . . receipt of research funds, the same constitutional limitation will not apply.” NAT'L COMM'N, REPORT, *supra*, at 78–79. Even as to research the federal government did not fund, the Commission observed that the matter “has not yet been definitively settled,” and that the courts would probably “permit regulation of nonfunded activities when reasonably related to the purpose of the federal spending.” *Id.* at 77; *see also* Hamburger, *supra* note 6, at 351–52.

⁴⁰ The FDA uses IRBs to license research on unlicensed drugs and devices, which otherwise are generally barred from being introduced into interstate commerce. Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 355(a) & (f), 360(e) & (g). Although the Food, Drug, and Cosmetic Act and the associated regulations raise constitutional questions similar to those discussed here, these problems could easily be avoided with modest changes so that the exemptions would apply to any use of the drugs and devices, not just in research.

Another specialized use of IRBs appears in the HIPAA Privacy Rule, *supra* note 6, which relies on IRBs and “Privacy Boards” to license sharing or otherwise publishing specified health or scientific information. Although the Privacy Rule does not generally concern human subjects research and therefore is not at issue here, it evidently is subject to the same constitutional objection as the IRB laws.

Conditions on federal research grants are the most visible mechanism by which the federal government imposes IRBs.⁴¹ The federal government awards its grants for the human subjects research conducted by particular scholars, but it channels its grants through universities and other institutions. Before making even one grant for one professor, it requires an institution generally to provide an “assurance” about the conduct of human subjects research at the institution, whether by faculty, students, or other personnel.

An initial commitment required in the assurance concerns ethical principles. Each institution receiving federal funds must first have assured the government that all human subjects research at the institution, regardless of its source of funding, will be conducted in accord with a statement of ethical principles. Although in theory an institution can propose its own statement of ethical principles, the government asks institutions to adopt its statement, the *Belmont Report*, which thus becomes the government’s default standard for the licensing.⁴² The government, in fact, has hardly ever accepted an alternative statement of ethical principles, and almost all institutions therefore take the hint and agree to the *Belmont Report*. The very notion of a single, institutional statement of ethical principles is rather astonishing, because individual researchers necessarily adopt different ethical principles—depending on their different views and depending, for example, on whether they are testing blood or questioning a Klansman. Nonetheless, universities are required to commit that all research done by their personnel on human subjects will comply with a uniform statement of ethical principles approved by the government.

A second commitment binds each institution to adhere to the Common Rule, which sets the basic standard for licensing under the IRB laws.⁴³ It acquired its name because it was adopted by seventeen federal agencies and departments, and it outlines how each institution must establish one or more IRBs and how each IRB must license human subjects research. The federal government initially asks each institution receiving grants for human sub-

⁴¹ For the conditions, see 45 C.F.R. § 46.101(a) (2005). The regulations refer to human subjects research “supported” by the government so as to include even research that gets only the most minimal support, such as the loan of a book. The current authorizing statute states, in part:

The Secretary shall by regulation require that each entity which applies for a grant, . . . for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit . . . assurances . . . that it has established (in accordance with regulations . . .) a board (to be known as an “Institutional Review Board”) to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

⁴² U.S.C. § 289(a) (2000).

⁴³ 45 C.F.R. § 46.103(b)(1) (2005); U.S. DEP’T OF HEALTH AND HUMAN SERVS., FEDERALWIDE ASSURANCE (FWA) FOR THE PROTECTION OF HUMAN SUBJECTS FOR INSTITUTIONS WITHIN THE UNITED STATES (2006) [hereinafter *FEDERALWIDE ASSURANCE*], available at <http://www.hhs.gov/ohrp/humansubjects/assurance/filasur.rtf>.

⁴³ 45 C.F.R. pt. 46 (2005).

jects research to commit that it will comply with the Common Rule for all such federally funded research at the institution.⁴⁴ In addition, however, the government asks each such institution to commit to the Common Rule for all other human subjects research, and although this further commitment is said to be “[o]ptional,” it has not always really been optional.⁴⁵

Other commitments get made in other ways. Supplementing the assurance are the “Terms of Assurance,” which add conditions that are too detailed for the assurance form. The Terms of Assurance are incorporated by reference to the assurance form, and the government thereby can use the Terms to clarify what it expects.⁴⁶ The government, moreover, can refuse to accept an assurance, and it often has withheld its acceptance of an institution’s assurance until the institution commits itself to additional requirements.⁴⁷

Institutions meet their assurances primarily by establishing IRBs, which then license human subjects research in accord with the Common Rule. Although the IRBs conduct the licensing, the institutions must remain involved in at least two ways. First, the institutions must ensure that their IRBs adhere to the Common Rule and other government expectations. Second, the institutions must ensure that all of their students, faculty, and other personnel submit to the IRBs.

The scope of the IRB licensing of human subjects research is apparent from the Common Rule’s definition of a “human subject.” He or she is “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.”⁴⁸ This definition covers at the very least (1) invasive procedures and (2) the reading of medical records. In addition, however, it includes perfectly ordinary inquiry—as when, for example, a law professor studies tax law (1) by talking with an IRS official or a tax practitioner or (2) by reading publicly available court records. The former is an interaction that produces data, and the latter reveals what IRBs consider “[i]dentifiable private information”—on the ground that it is “information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.”⁴⁹ Thus, a human subject is not merely the object

⁴⁴ FEDERALWIDE ASSURANCE, *supra* note 42.

⁴⁵ *Id.* For the pressures to make the optional commitment, see *infra* text accompanying note 95.

⁴⁶ FEDERALWIDE ASSURANCE, *supra* note 42; U.S. DEP’T OF HEALTH AND HUMAN SERVS., TERMS OF THE FEDERALWIDE ASSURANCE (FWA) FOR INSTITUTIONS WITHIN THE UNITED STATES (2006), <http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm> [hereinafter TERMS OF ASSURANCE].

⁴⁷ See, e.g., *infra* text accompanying note 95.

⁴⁸ 45 C.F.R. § 46.102(f) (2005).

⁴⁹ *Id.* This example is based on all too many instances in which professors, including law professors, are required to get prior permission, are reprimanded and asked to apologize for having failed to get permission for earlier articles, or are told that they will be prevented from publishing already accepted articles unless they convince the IRB that the research would have received permission.

of some ghastly invasion of his body, but also someone whose voluntary conversation or public legal records are a matter of interest to the researcher. This very Article, for example, is based on extensive consultations with all sorts of researchers who do not want to be identified (lest their IRB or university learn of their complaints and penalize them). It is also based on information that IRB members reveal about themselves in communications with researchers (such as orders to researchers that they stop inquiry or requests that they modify their research so as not to disclose or publish, etc.). This Article thus relies both on data obtained through “interaction with the individual” and on “[i]dentifiable private information.”

Any research on human subjects must ordinarily get prior permission from an IRB. As summarized by the Terms of Assurance, “all human subject research” must “be reviewed, prospectively approved, and subject to continuing oversight and review at least annually by the designated IRB(s),” and the IRBs “have authority to approve, require modification in, or disapprove the covered human subject research.”⁵⁰ IRBs rarely go so far as to disapprove research, for they can fully control what is done through modifications, and they require modification of approximately 80% of all research that is submitted for approval.⁵¹

Although the Common Rule exempts some research from the requirement that human subjects research get IRB “approval,” even this exempt research needs prior permission. The government uses its guidance to supplement the requirements of the Common Rule, and OHRP—the Office for Human Research Protections at HHS—“recommends” that institutions prevent “the investigator” from “determin[ing]” for himself “whether pro-

Even the study of published data sets, such as census data, are human subjects research to the extent that researchers can discern the identity of persons covered by the data. Thus, when the *IRB Guidebook* suggests that work on census data need not be subject to IRBs, it carefully refers to “anonymous U.S. Census data.” OFFICE FOR PROTECTION FROM RESEARCH RISKS, U.S. DEP’T OF HEALTH AND HUMAN SERVS., PROTECTING HUMAN RESEARCH SUBJECTS: THE INSTITUTIONAL REVIEW BOARD GUIDEBOOK ch. V, pt. A (1993) [hereinafter *IRB GUIDEBOOK*].

IRBs can publish general determinations that research on some types of information, such as census data and other publicly available data sets, are exempt, but because OHRP “recommends that institutions” prevent “the investigator” from “determin[ing]” for himself “whether proposed research is exempt from the human subjects regulations,” IRBs feel obliged at the very least to have researchers “register” their research on such data sets with the IRB—so that the IRB can intervene if it wishes. OFFICE FOR HUMAN RESOURCE PROTS., DEP’T OF HEALTH AND HUMAN SERVS., GUIDANCE ON WRITTEN IRB PROCEDURES § D(1) (July 11, 2002), <http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd702.htm> [hereinafter *GUIDANCE ON WRITTEN IRB PROCEDURES*]; see also *IRB GUIDEBOOK*, *supra*, at ch. I, pt. C. For the “registration,” see, for example, the registration requirement of the University of Chicago, Social & Behavioral Sciences Institutional Review Board, Policy on Public Use Data Sets, <http://humansubjects.uchicago.edu/sbsirb/publicpolicy.html> (last visited Nov. 10, 2006).

⁵⁰ TERMS OF ASSURANCE, *supra* note 46, at pt. 5.

⁵¹ Hamburger, *supra* note 6, at 345 & n.172.

posed research is exempt from the human subjects regulations.”⁵² As a result, IRBs typically expect researchers to submit their proposals for exempt research to the IRB. Exempt research thus gets reviewed more quickly than other research, but it equally needs to get permission.⁵³

The standards by which IRBs review research proposals are very open-ended. The central standard is the Common Rule’s requirement that the “[r]isks to subjects” must be “minimized” and that the risks must be “reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.”⁵⁴ This requirement that IRBs evaluate the importance of the knowledge—meaning, the knowledge that will be published—is an early hint of the degree which this review of research is really licensing of speech and the press. More generally, it will be seen that this federal standard for permitting or suppressing research leaves IRBs much discretion, including a freedom to consider the local standards of their institutions. As OHRP tells IRBs, “[t]he risk/benefit assessment is not a technical one valid under all circumstances; rather, it is a judgment that often depends upon prevailing community standards and subjective determinations of risk and benefit.”⁵⁵

Finally, individual teachers and students must comply with the demands of their IRB because of a range of pressures. Universities warn of “serious consequences” for personnel who fail to conform to the demands of the IRB, and administrators sometimes are helpful enough to clarify that noncompliant researchers can be fired.⁵⁶ IRBs, however, do most of their

⁵² GUIDANCE ON WRITTEN IRB PROCEDURES, *supra* note 49, at § D(1); *see also* IRB GUIDEBOOK, *supra* note 49, ch. I, pt. C. For an illustration of how OHRP also uses assurances to impose this requirement, *see infra* note 108.

⁵³ IRBs can list some categories of research—for example, the study of publicly available data sets—so that they will be considered exempt without specific review, but IRBs tend to require that researchers “register” such research with the IRB—so that the IRB can intervene if it wishes and so that it has a record of the research in case the government inspects the IRB. *See, e.g., supra* note 49. Although federally organized registration of research is not quite as worrisome as federal licensing, it is not exactly reassuring.

Some research is eligible for “expedited review,” but this is simply the truncated review that does not require a meeting of all of an IRB’s members. 45 C.F.R. § 46.110 (2005).

⁵⁴ 45 C.F.R. § 46.111(a)(1)–(2) (2005). The Common Rule adds:

In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

Id. at § 46.111(a)(2).

⁵⁵ IRB GUIDEBOOK, *supra* note 49, at ch. III, pt. A.

⁵⁶ University of Chicago, Social and Behavioral Sciences Institutional Review Board, Frequently Asked Questions 8, <http://humansubjects.uchicago.edu/sbsirb/faq.html> (last visited Nov. 10, 2006). At a meeting held by the Northwestern University IRB, when a representative of the IRB referred to such consequences, a law professor asked what would happen if she went ahead without approval, and was told that there would be disciplinary action at the highest levels and severe sanctions. The IRB representative also said that nonconforming students could have their diplomas withheld and that faculty might

own enforcement. According to OHRP, “[w]hen unapproved research is discovered, the IRB and the institution should” not only “act promptly to halt the research” but should also “address the question of the investigator’s fitness to conduct human subject research.”⁵⁷ If it finds him unfit (even if merely for failing to ask for prior permission), the IRB can prevent him from doing other research on human subjects.⁵⁸ More typically, an IRB will simply take into account a researcher’s prior “virtue” or “track record” of cooperation with the IRB when making decisions about his proposals.⁵⁹ The researcher, moreover, has no recourse against the IRB, because its proceedings are secret, and there is no appeal.⁶⁰ In these circumstances, re-

even be dismissed. This account comes from a conversation I had with Professor Cynthia Bowman from the Northwestern University School of Law on December 10, 2004.

⁵⁷ IRB GUIDEBOOK, *supra* note 49, at ch. I, pt. D. Strikingly, it adds: “Beyond the obvious need to protect the rights and welfare of research subjects, the credibility of the IRB is clearly at stake.” *Id.*

⁵⁸ Almost no one consulted for this Article or my prior article on IRBs was willing to be cited by name, lest their IRB consider them uncooperative. The repercussions feared by such persons include the possibilities that their IRB will subject their future research to extra scrutiny, that it will deem them not “fit” to do research, and that it will seek to have them fired—a threat that high level administrators sometimes make explicit. The unwillingness of academics to provide information except anonymously is also noted by at least one journalist who has written on the subject. Cary Nelson, *Can E.T. Phone Home*, ACADEME, Sept.–Oct. 2003, at 30, 35 (2003). Even anonymous stories (about ruined research or about threats from IRBs) must be cited in publications such as this without the sort of detail that would allow identification, and this is one of the reasons there are relatively few textured accounts of how the licensing system actually works.

Indeed, the oldest independent IRB in the country declares: “IRBs have the authority to approve, require modifications to, or disapprove the proposed study protocols and consent forms for research, which will involve human subjects. In addition, IRBs must review and approve or disapprove the investigator for the research.” Press Release, Western Institutional Review Board, WIRB First Independent to Achieve Accreditation for Work Safeguarding Rights of Human Research Subjects (May 1, 2003), http://www.wirb.com/shell.php?content=content/foot_wirb_news_archive.

⁵⁹ As Robert Levine explains,

many IRBs take the investigator’s “virtue” into account in making decisions about protocols. For example, Shannon and Ockene report on their IRB’s disapproval of a low risk protocol based, in part, on the fact that the investigator had a poor relationship with the IRB In the same paper, they report their IRB’s approval of a high risk protocol; one important factor was that the investigator had “an excellent track record in terms of trustworthiness, exemplified by his willingness to report immediately any problem in research by notifying the appropriate people.” Moreover, “within the medical center . . . he was perceived to be skilled and trustworthy.”

ROBERT J. LEVINE, *ETHICS AND REGULATION OF CLINICAL RESEARCH* 27 (2d ed. 1986).

⁶⁰ In many ways, the procedures of IRBs come very close to the old inquisitorial process. Like inquisitorial courts, an IRB can proceed on its own information or that submitted by an informer. For example, in addition to reviewing submitted proposals, an IRB will sometimes collect information about violations by surveying the publications of its institution’s faculty to determine whether they have conformed to the licensing regulations. Supplementing their own efforts, IRBs also make clear that they are open to receiving complaints from anonymous informants, who sometimes abuse the system to accuse their academic or political enemies of violating IRB requirements. Whatever the source of its information, the IRB then proceeds to act both as prosecutor and as judge. In its prosecution, moreover, the IRB seeks the confession and reformation of the accused. It investigates by demanding information from the accused researcher, who is often not told about the details or range of the accusations. Such requests for information are part of a broader pattern in which researchers must report their own failures to comply with IRB requirements, and a failure to report oneself is in itself a violation. When the accused re-

searchers hesitate to defy their IRB, lest they risk their future research and their careers. Most fundamentally, researchers recognize that IRB licensing is authorized by law, and although it may be doubted whether the government in imposing the IRB system is really acting in accord with law, researchers tend to submit to the licensing because the law apparently requires them to do so.

B. The Licensing of Speech and the Press

The primary constitutional problem with this system is that the IRB laws expressly impose licensing on speech and the press. The laws are said to concern research rather than speech or the press, and on this assumption it is often casually taken for granted that the IRB laws are merely regulations of conduct. The IRB laws, however, regulate research by expressly imposing licensing on speech and the press—indeed, on verbal language—and these laws therefore are of the sort most centrally and severely forbidden by the First Amendment's guarantee of speech and the press.

1. The Irrelevancy of Doctrines from the Periphery.—In examining how the IRB laws license speech and the press, one must keep in mind that the Supreme Court's doctrines from the periphery of the freedom of speech and the press are not necessarily applicable to the core freedom from licensing. In particular, the Court's doctrines on the speech–conduct distinction, content neutrality, and different subjects of expression (which were developed to manage questions about injunctions, post-publication restraints, and a broadly defined expression) are not necessarily useful guides as to what laws *license* speech or the press. One could attempt to use the judicial doctrines from the periphery to show that the IRB laws license speech and the press, but on the whole the application of these doctrines to the central question of licensing introduces more confusion than clarity. They were formulated to define and thus delimit an otherwise expansive freedom of speech and the press, and they therefore must be viewed with caution when applied to the previously unqualified core freedom from licensing.

The Supreme Court's doctrines on speech and conduct are not really designed to sort out laws on speech from those on conduct. The Supreme Court sometimes understands the First Amendment to forbid laws restraining conduct (such as flag-burning) and sometimes understands the Amendment to allow laws restraining speech and the press (such as defamation and fraud), and the Court therefore cannot simply distinguish laws on speech from those on conduct. Instead, it must distinguish between speech and conduct within a broader analysis that cuts across any speech–conduct dis-

searcher is responding to the IRB's investigation, he is usually advised that he can minimize the damage to his research and his career by showing remorse and being submissive. In contrast, he risks harsher treatment if he denies the accusation, hires a lawyer, or otherwise seems defensive, for this is taken as a lack of cooperation and respect for the IRB. In these circumstances, the safest course of action is usually confession, for this is apt to be considered a sign that one will be compliant in the future.

tion. Thus, its doctrine distinguishing speech from conduct is designed to feed into the more expansive analysis in which neither speech nor conduct has any ultimate significance—in which conduct sometimes is protected as speech, and speech sometimes is not protected. It therefore cannot be assumed that the Court's doctrines on the speech–conduct distinction are really designed to sort out which laws license speech or the press.

In fact, the Court developed its doctrines on conduct, content neutrality, and different subjects of expression at the periphery of the freedom of speech and the press, and thus far from being a measure of when a law licenses speech or the press, these doctrines endanger the core freedom from licensing. When the Supreme Court extended the First Amendment to protect against injunctions and post-publication restraints, let alone when it expanded speech to mean expression, the Court had to explain that some injunctions and post-publication restraints that directly targeted speech and the press (including the laws on defamation and fraud) were nonetheless constitutional, and this made sense, for to the extent the Constitution no longer strongly distinguished among different methods of regulation, the Court had to distinguish among different types and uses of speech. Yet it is one thing to make an expansive freedom plausible by devising doctrines that cut back on it at the outer edges; it is quite another to apply such doctrines to an already limited core freedom. In this way, the Court's doctrines, which were necessary to prevent the expanded portion of the freedom from obliterating familiar and valuable laws, have ended up weakening the core freedom from licensing. In particular, the Court's doctrines have come to suggest that laws licensing speech or the press can sometimes be constitutional—especially if the laws mention conduct, are content neutral, or do not concern expression of political or other public significance.

These doctrines from the periphery, however, have no place in the core freedom from licensing, and thus, for example, although conduct can sometimes mask the after-the-fact regulation of speech or the press, it cannot mask the *licensing* of speech or the press. Talking creates noise, writing uses pencils, and printing uses machinery, but although it generally is constitutional under the First Amendment to make laws licensing noise, lead, and machinery to prevent their harms, it is quite another matter to make laws licensing the creation of noise while talking, the use of pencil leads for writing, or the operation of machinery for printing.⁶¹ Perhaps some laws penalizing such things could be constitutional, but not laws licensing them, for such laws would require licensing of verbal language, and it is simply not plausible that the government can escape the prohibition against licensing speech and the press merely by adjusting the laws so that they also refer to conduct. Thus, the government can make a law licensing driving; but it cannot make a law generally licensing public speaking, oral interviews, or

⁶¹ The English licensing laws, for example, included provisions licensing printing presses. DECREE OF STARRE-CHAMBER, *supra* note 16, at sig. C3[v], §VII (1637).

written surveys; nor can it legitimize any such law by turning it into a law that licenses driving in order to distribute surveys or in order to attend an interview or speaking engagement. A licensing law's allusion to conduct cannot cloak its allusion to verbal language.

Similarly, although content neutrality can sometimes protect a post-publication restraint from constitutional challenge, it cannot preserve a law licensing speech or the press. The English licensing laws of the seventeenth century, whether those of the Star Chamber or of Parliament, centrally prohibited any printing without a license, and although such provisions were content neutral, they were the model of what the speech and press clause of the First Amendment forbade.⁶² Thus, even if content neutrality is a useful measure for post-publication restraints, it cannot justify a law that requires licensing.

Nor can the non-political subject of expression give legitimacy to a law licensing speech or the press. Today, in the expanded sphere of freedom of speech and the press, it often seems necessary to distinguish among various injunctions and post-publication restraints by examining the subject matter of the expression at stake, it being commonly assumed, for example, that political expression is more valuable than other expression. The seventeenth-century licensing laws, however, both in England and in Italy, required permission for all kinds of printing, whether poetic, academic, scientific, or political, and far from being concerned primarily with political expression, the pre-eminent critics of the licensing laws, Milton and Locke, emphasized the danger to academic inquiry, including not only the licensing of what scholars could print but also the implications for what they could read.⁶³ Against the background of these content-neutral licensing laws and the not merely political protest against them, the First Amendment did not distinguish among different subject matters or forms of speech or the press. Thus, even if a licensing law focuses on poetic, social, academic, or scientific words, it still violates the freedom of speech and the press. Perhaps ideas about political expression are useful for sorting out which injunctions and post-publication restraints are permissible, but they can only diminish the freedom from licensing.

Of course, beyond the narrow sphere of *licensing* laws, a law can expressly regulate conduct, verbal language, or some combination thereof, without necessarily being a law that abridges the freedom of speech or the press. For example, as already noted, a law can expressly impose at least some post-publication restraints on verbal fraud or defamation and not violate the First Amendment. Yet this does not mean that a law can constitutionally *license* speech or the press to prevent fraud or defamation, and this

⁶² *Id.* at sig. B2[r], §II.

⁶³ For Milton, see, for example, quotations cited in *infra* note 195. For Locke, see John Locke, *Common's Resolutions on the Licensing Bill* (1695), reprinted in *SOURCES OF ENGLISH CONSTITUTIONAL HISTORY* 619 (Carl Stephenson & Frederick George Marcham eds., 1937).

holds even if the law refers to conduct as well as verbal language, even if it is content-neutral, and even if it refers to poetry rather than politics.

Thus, to preserve the core freedom from licensing speech or the press, the doctrines that were developed to define the expanded periphery must be kept away from the core. In particular, the Supreme Court doctrines on the speech–conduct distinction, on content neutrality, and on different subjects of expression have no place within the core and should not be allowed to mask the violation that occurs when a licensing law specifies or otherwise targets verbal language. The Court’s doctrines are necessary to determine the boundaries of the freedom that expands out to injunctions, post-publication restraints, and non-verbal expression, but precisely because these doctrines were designed to qualify protection at the periphery, they are a threat to the freedom of speech and the press when applied to the unqualified, core freedom from licensing.

2. *How the IRB Laws Target Speech and the Press.*—How then do the licensing provisions of the IRB laws target speech and the press? The answer begins with “research” but quickly becomes more specific.

The Common Rule establishes licensing of “research,” and perhaps this alone would be unconstitutional—not necessarily because of some newly-minted right of research, but more simply because the Common Rule adopts the modern conception of scientific research. In the modern ideal of research, individuals must seek hypotheses, theories, or other general statements and then must publish these so they can be tested by other individuals. In the course of testing the prior statements and showing them to be erroneous, these other individuals seek and disseminate their own theories, which refine or even reject those which came before, and scientific research thus is a continuing process of proposing and publishing theories or general statements. Accordingly, when the Common Rule establishes licensing of “research,” it would seem to impose licensing on attempts to formulate theories or general statements, whether spoken or printed, and it would even seem to impose licensing on the publication of these statements. In both ways, the Common Rule apparently requires licensing of speech and the press.

Yet such analysis of the word “research” in the Common Rule need not remain speculative, for the Common Rule defines “research” in terms of verbal statements, and the Common Rule thus leaves no doubt that it directly establishes a system of licensing speech and the press. The Common Rule adopts the modern, scientific conception of research and therefore recites that “research” means “a systematic investigation . . . designed to develop or contribute to generalizable knowledge.”⁶⁴ Already when focusing on “research,” the Common Rule imposes licensing on inquiry, and by specifying that “research” is an “investigation” designed to produce “gener-

⁶⁴ 45 C.F.R. § 46.102(d) (2005).

alizable knowledge,” the Common Rule clarifies that it imposes licensing on inquiry with intent to learn. Indeed, by using the phrase “generalizable knowledge,” the Common Rule imposes licensing on inquiry with intent to learn such knowledge as can be reduced to hypotheses, theories, or general statements. As already suggested, scientific knowledge ultimately consists of such generalizations, and thus in singling out the pursuit of “generalizable knowledge,” the Common Rule directly imposes licensing on account of attempts to produce the generalizations that constitute scientific knowledge.

Not content with this candid reference to scientific generalizations or theories, the government asks institutions to acknowledge that “generalizable knowledge” means what is expressed. When universities and other institutions qualify for federal grants by assuring the federal government that they will impose IRBs on their personnel, the government also asks the institutions to commit to “the ethical principles” stated in the *Belmont Report*, which explains that “the term ‘research’ designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).”⁶⁵ This echoes the words of the regulation that would become the Common Rule, and rather than merely give an unconstitutional interpretation to a constitutional law, it explains—what is clear enough from the words of the Common Rule—that the Rule requires licensing of attempts to develop or contribute to knowledge “expressed” in theories or statements.

As if this were not bad enough, in the scientific model adopted by the Common Rule, “generalizable knowledge” is publishable knowledge. The government is careful not to mention the word “publication” in its formal definition of research, but both the government and IRBs recognize the conventional understanding that scientific or generalizable knowledge is that which can and should be published. A report of a committee of the National Institutes of Health (“NIH”) provides a convenient overview. Because the Common Rule defines “research” in terms of what is “designed” to produce generalizable knowledge, the IRB representatives consulted by the NIH committee “agreed that an activity would be considered research” and thus would be subject to IRBs “if the investigator plans to publish the findings.”⁶⁶ Beyond this basic situation, it appeared to the committee that

⁶⁵ FEDERALWIDE ASSURANCE, *supra* note 42; THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, REPORT OF THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, 44 Fed. Reg. 23,192, 23,193 (Apr. 18, 1979) [hereinafter BELMONT REPORT]. As will be seen later, an institution can attempt to get the government to accept another statement of ethical principles, but the *Belmont Report* clearly is the default standard. See *infra* note 136 and accompanying text.

⁶⁶ COMM. ON THE ROLE OF INSTITUTIONAL REVIEW BDS. IN HEALTH SERVS. RESEARCH DATA PRIVACY PROT., DIV. OF HEALTH CARE SERVS., INST. OF MED., PROTECTING DATA PRIVACY IN HEALTH SERVICES RESEARCH 53 (2000).

IRBs adopt different understandings of the phrase “generalizable knowledge”—some IRBs concentrating on intent to publish, and others looking beyond intent toward actual dissemination:

Some IRBs interpret this phrase to cover only projects in which the investigator intends to publish the results, whereas others interpret the phrase as covering projects whose results are disseminated beyond the department or unit conducting the study, for example, dissemination through oral presentations at scientific or other professional meetings.⁶⁷

A third, more typical, interpretation asks more generally whether the knowledge will be publishable, and it is this approach that the committee uses in its own analysis. This approach often gets discussed when IRBs decide whether to claim jurisdiction over Quality Assurance and Quality Improvement studies on the ground that they are “research,” for although these studies are primarily designed to improve care for patients, they sometimes come to have broader implications and thus give rise to publishable information. In these circumstances, even if not designed to produce generalizable knowledge, a study must get licensed. As the NIH committee observes, “projects that start as QA or QI may turn out to be publishable and then require IRB approval.”⁶⁸ Thus, not only does the Common Rule impose licensing on the pursuit of “generalizable knowledge,” but also this knowledge is widely recognized to mean what is designed to be “publish[ed]” or is “publishable.”⁶⁹

In fact, under the Common Rule, IRBs enjoy authority to require researchers to get prior permission for the full range of observing, reading, talking, asking, writing, printing, and publishing involved in research. IRBs typically force scholars either to avoid asking sensitive questions or to avoid learning and publishing the identity of the persons about whom information is collected (including both the persons asked and those they talk about). IRBs often impose this choice even when researchers only study persons through published records, such as census data or court records. Faced with a difficult choice between censorship as to one sort of information or another, a biological or social sciences researcher will usually forgo

⁶⁷ *Id.* at 43.

⁶⁸ *Id.* at 43 n.3.

⁶⁹ For another illustration that “generalizable knowledge” means what is designed to be published, one need only consult the National Science Foundation, which poses the question: “Does research conducted as a classroom exercise count as human subjects research?” It answers:

The Common Rule defines research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (§ 102.d)

This includes activities which are intended to lead to published results Classroom exercises, involving interactions with human participants, which are part of an educational program, and are not designed to advance generalizable knowledge, are not covered by this regulation.

National Science Foundation, Frequently Asked Questions and Vignettes, <http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp> (last visited Nov. 9, 2006).

collecting or publishing the information about the identity of his subjects, and a humanist writing a biography will usually give up learning or publishing other information.⁷⁰ IRBs frequently even require researchers to protect the privacy of subjects by destroying their research notes and other data—thus ensuring that the research cannot be replicated and that the underlying information cannot be shared or reused for other projects. To make matters worse, when an IRB learns that human subjects research has been accepted for publication but has not yet been published, it sometimes will tell the author not to publish, unless he first persuades the IRB that the research would have been given permission.⁷¹ All of this is direct suppression of speech and the press under authority of federal law.

As it happens, IRBs often impose their limits through informed consent forms. Informed consent will shortly be considered on its own terms, but already here it must be noted that IRBs typically limit what a researcher can ask, say, disclose, or otherwise publish by denying him permission until he agrees to put these restraints in his informed consent form. IRBs therefore claim that they usually only modify consent forms, not research or its publication. This, however, is little more than an attempt to fly under the radar, and it cannot disguise the reality of the licensing. The use of consent forms to specify licensing restrictions does not diminish the blatant interference with speech and the press.

Incidentally, even if the IRB laws did not expressly refer to verbal language, their “content discrimination” would reveal that in reality they require licensing of speech and the press. Although content discrimination is a familiar element of First Amendment doctrine, it can also be understood more simply as a reality check—as a means of looking beyond the formal requirements of the law to discern whether in reality it requires licensing of speech and the press—and thus even if the IRB laws were silent about “generalizable knowledge,” their discrimination would reveal that they actually required licensing of speech and the press.⁷² Imagine that the IRB

⁷⁰ In many social science surveys, the identities of the persons studied do not need to be published, but the IRB will often go so far in protecting the subjects from any disclosure or publication that they prevent the researchers from learning the identity of the persons surveyed, thus preventing follow up inquiries and reducing the efficacy of the study.

⁷¹ For example, the University of Illinois IRB took this approach to a professor of literature who had an article accepted in the *Kenyon Review*. See *infra* note 116. An IRB at another major university recently gave such a warning to a law professor. For other examples, at George Washington University and the University of Pittsburgh, see Hamburger, *supra* note 6, at 303 n.86. Although such incidents have occurred with some regularity, researchers are too afraid of the IRBs to complain, and others take the censorship for granted. As Harold Edgar and David Rothman observe about the George Washington incident, “a committee established pursuant to federal law directed academics not to publish their research, and no widespread discussion of First Amendment implications has ensued.” Harold Edgar & David J. Rothman, *The Institutional Review Board and Beyond: Future Challenges to the Ethics of Human Experimentation*, 73 *MILBANK Q.* 489, 499 (1995).

⁷² For the conventional use of the term “content discrimination,” see *Simon & Schuster v. Crime Victims Bd.*, 502 U.S. 105 (1991).

laws applied not to scientific “research” or “investigation” by institutional researchers, but to journalistic investigation by newspaper reporters. Rather than IRBs, the laws would require NRBs—Newspaper Review Boards—and each newspaper reporter would have to get permission from his newspaper’s NRB before beginning any investigation. In imitation of an IRB, the NRB would be composed of fellow journalists and at least one community member, and it would require each journalist to submit a list of his questions and other investigative plans. It could deny him permission to ask about or publish matters it considered too “sensitive,” that might put a “human subject” at risk of undefined legal, economic, or psychological harms, or that otherwise offended “prevailing community standards and subjective determinations of risk and benefit.”⁷³ For example, it could deny him permission to investigate and publish his results if there were “a risk that the group to which the subject population belongs will be stigmatized.”⁷⁴ The NRB could also require the journalist not to inquire about or publish the names of his “human subjects” or any other identifying information; it could demand that he not share any information with fellow journalists unless he got further permission from the NRB; it almost certainly would insist that he destroy any identifiers in his notes and any audio recordings of interviews after his initial use of these materials. In justification, the government would observe that “research is a privilege, not a right” and that journalistic investigations carry the risk of legal, social, reputational, and emotional harms for their human subjects.⁷⁵ This targeting of journalistic investigation by journalists would probably be a form of unconstitutional content discrimination even if it were only the basis for post-publication restraints.⁷⁶ Here, more seriously, where the content discrimination—the targeting of research by institutional researchers—is the basis for licensing, the discrimination provides a further indication that in reality the IRB laws impose licensing on speech and the press.

Similarly, if one were to continue to doubt whether the IRB laws impose licensing on speech and the press formally, the overinclusiveness of

⁷³ IRB GUIDEBOOK, *supra* note 49, at ch. III, pt. A.

⁷⁴ This language comes from my own conversations with IRB members.

⁷⁵ For the astonishing government claim that “research is a privilege, not a right,” see *supra* note 112, and Hamburger, *supra* note 6, at 353. For the variety of harms, see *infra* note 145 and accompanying text.

⁷⁶ Some advocates of IRBs aspire to extend the licensing to journalism, and already in the early 1980s, John Robertson—who had served as an advisor to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research—concluded that

Social scientists thus are treated no differently from journalists. Both are subject to employer constraints [B]oth are subject to restrictions attached to grants of public funds. If the government gave grants to newspapers to foster investigative reporting, it could, as it does with human subject research funds, condition them on reporters having a publisher’s ethics committee approve their investigative techniques.

John A. Robertson, *The Social Scientist’s Right to Research and the IRB System*, in *ETHICAL ISSUES IN SOCIAL SCIENCE RESEARCH* 356, 363 (Tom L. Beauchamp et al. eds., 1982).

the IRB laws would reveal that they do so in reality.⁷⁷ For example, by establishing the licensing of human subjects investigations designed to produce generalizable knowledge, the Common Rule includes a vast amount of research in the social sciences and the humanities, including literary, religious, historical, and legal inquiry. Although IRBs once tended to shut their eyes to much of this merely verbal research, they increasingly recognize that it comes within the Common Rule and therefore must be licensed. IRBs, for instance, now often tell law professors that they need permission before they can proceed with their research—even if their research consists solely of reading court records or talking to judges, lawyers, or businessmen.⁷⁸ It might be thought that such instances merely illustrate what is called “mission creep,” and that if such excesses are not required by law, they are not relevant. Yet as the federal government recently acknowledged, the licensing of mere talk is required by the Common Rule. Historians in 2003 asked the federal government to exempt “oral history,” which is interviewing for historical purposes, but the federal government correctly answered that oral history was necessarily covered if it was done systematically for generalizable knowledge.⁷⁹ In this manner, the law inescapably requires licensing of entire fields of inquiry that consist of mere speech and the press.

Even in the biomedical sciences and the scientific side of the social sciences, the IRB laws require licensing for research that consists of nothing more than speaking and printing. For example, when an epidemiologist or social scientist seeks to ask questions in a survey—whether he is putting the questions to government officials or to the general public—he usually must first submit his questions to the IRB for permission so that the IRB can soften or remove “sensitive” questions, so that it can require that the researcher not ask for or publish identifying information, and so that it can

⁷⁷ Rather than a direct application of the Supreme Court’s overbreadth test, this is simply an attempt to discern whether a law that *formally* does not constrain speech or the press is, *in reality*, such a law. The degree of overbreadth that matters in Supreme Court doctrine remains elusive precisely because overbreadth often serves as a reality test rather than an independent limitation on the government. A hint of this can be observed when the Court in *Virginia v. Hicks* explains that “[r]arely, if ever, will an overbreadth challenge succeed against a law or regulation that is not specifically addressed to speech or to conduct necessarily associated with speech (such as picketing or demonstrating),” 539 U.S. 113, 124 (2003)—to which one might add research.

⁷⁸ For example, one such professor was told that he needs prior permission to analyze any court record when it contains identifying information, such as names. The name of the professor cannot be published here, for like almost all persons who need IRB approval, he must worry that if the IRB thinks he has been complaining, it will deem him uncooperative and will review his research more severely, thus preventing him from doing his work. As it was, because he had already published some articles based on court records, he was advised by the IRB administrator to apologize and show that he was contrite.

⁷⁹ See Oral History Ass’n, Oral History Excluded from IRB Review, http://omega.dickinson.edu/organizations/oha/org_irb.html (last visited Nov. 9, 2006); Linda Shopes & Donald Ritchie, Exclusion of Oral History from IRB Reviews: An Update, <http://www.historians.org/Perspectives/Issues/2004/0403/0403new1.cfm> (last visited Nov. 9, 2006).

place restrictions on any transfer and use of the responses, such as by demanding that they be destroyed after several years.⁸⁰ Epidemiologists and social scientists have long been careful with the information they collect, but they now must get permission for merely verbal inquiry, and they often do not get it. Thus, when some scholars recently sought to survey federal officials about other federal officials, the scholars first had to get permission from the IRB, which barred them from asking about or publishing the identity of the officials who responded.⁸¹ Both in the humanities and in the sciences, the Common Rule is so expansive that it inevitably requires licensing of entire fields of research that consist of nothing more than speaking and printing; and this is the sort of overinclusiveness that should reveal even a law ostensibly licensing conduct to be, in fact, a law licensing speech and the press.

This sort of reality check, however, is unnecessary, because the IRB laws expressly impose their licensing on verbal language. It has been seen that these laws explicitly require licensing of attempts to produce “generalizable knowledge,” which is recognized to mean what can be “expressed” in scientific theories or general “statements.” In this way, as is widely acknowledged, the laws even require licensing of what a person “plans to publish.”

One might still protest that much research, particularly medical research, includes conduct as well as speech and that some of this conduct can be dangerous. If one is worried about drug testing, however, one should remember that the FDA regulations and their use of IRBs for drug testing are not at stake here.⁸² If one is concerned about other intrusive medical and biological research, one should keep in mind that this would remain subject to other methods of regulation—ranging from negligence law to penalties on particular types of procedures. Even *licensing* of particular types of procedures would be possible, as long as it did not focus on researchers or research. In short, the objection here is not against regulation, but merely against a single unconstitutional method of regulation.

Some commentators concede the First Amendment problems with IRBs in the humanities and social sciences but rely on doctrines about conduct, content neutrality, and political expression to insist that the IRB laws remain constitutional for medical and biological research—or at least for such research as requires physical intervention. From this perspective, medical and biological research involves more conduct than humanities and social sciences research, thus making it lawful if it is content neutral. This, however, misses the constitutional point. Just as the First Amendment’s religion guarantee focuses on a particular subject matter, so the Amendment’s

⁸⁰ IRB GUIDEBOOK, *supra* note 49, at ch. III, pt. A.

⁸¹ As in most such cases, the identity of the researchers cannot be published, lest the IRB deem them uncooperative and therefore subject their future research to more rigorous scrutiny.

⁸² See *supra* note 40.

speech and press guarantee focuses on a particular method of regulation, licensing. For other methods of regulation, conduct, content neutrality, and different subjects of expression offer useful distinctions that can perhaps justify a law. Licensing, however, is another matter. Under the First Amendment, a law that singles out speech or the press for licensing should be considered unconstitutional even if it also mentions or concerns conduct, even if it is content neutral, and even if it concerns an allegedly low value subject.⁸³

It is therefore irrelevant that much research involves conduct, for this cannot avoid the constitutional problem that arises when the law singles out verbal language for licensing. The Supreme Court's doctrines from beyond the core freedom from licensing often attempt to distinguish speech from conduct by looking at the regulated behavior, but the First Amendment's bar against licensing focuses on the law itself and whether it specifies or otherwise targets speech or the press. A law can in some circumstances specify speech or the press as the object of a penalty, but it cannot specify speech or the press for licensing, and only the introduction of doctrines from the periphery have led to doubts about this. Thus, the confusion as to whether the Common Rule has the effect of regulating speech or conduct is really a conceptual confusion—one that has arisen from the Supreme Court's doctrines on the periphery and that now threatens to undermine the core freedom from licensing.

To get some clarity about this, one need only consider, again, the notion of a Newspaper Review Board. If the government imposed NRB licensing on investigative journalism, the law would be unconstitutional even if much of the investigation involved conduct. For example, the NRB could deny the journalist permission to make observations or take photographs in places where people do not clearly expect to be studied (such as a restaurant); the NRB could bar him from becoming a Klansman as a means of studying the Klan (which is not a fictional example of what journalists do); it could prevent him from testing people for their racism; it could even prevent him from asking members of the public to test and give their evaluation of lawful consumer goods—particularly things that an NRB would be apt to consider sensitive or risky, such as condoms, tampons, pregnancy tests, hair dryers, or automobiles. Of course, all such conduct can be subject to some after-the-fact penalties, but the element of conduct obviously would not lend constitutionality to a law that required journalists to get prior permission from an NRB before doing an investigation designed to generate generalizable or otherwise publishable knowledge. This would be licensing of speech and the press.

⁸³ As to how some laws licensing use of government property can be distinguished, see *supra* text accompanying note 31.

3. *Informed Consent.*—Nested within the IRB system—not unlike a little Russian doll—is yet another licensing system, with the benign name, “informed consent.” Although this Article concentrates on the licensing conducted by IRBs, the informed consent requirement of the Common Rule reveals yet further licensing of speech and the press—licensing done by individuals under the auspices of IRBs.

This informed consent under the Common Rule is very different from the informed consent familiar from the practice of medicine. To avoid committing a battery, doctors and others frequently have reason to seek consent, and when doctors get this consent from their patients, they occasionally have reason to provide their patients with some information. The Common Rule, however, requires researchers to go through a much more detailed and formal informed consent process with their human subjects, and this creates a peculiarly democratized licensing, in which researchers must get written permission from individuals even before reading about them or asking them questions. Whereas a journalist or other individual can put questions to a subject without first proffering a legal document for signature, a researcher must first supply a printed warning about the risks of talking with the researcher and must get a signed consent form. Beforehand, moreover, the researcher must submit the proposed warning and consent form to the IRB for review, so that the IRB can make sure that the human subject will be sufficiently admonished about the dangers of talking with the researcher.

Of course, upon being asked to sign a highly detailed, printed legal document, many persons simply refuse to talk to researchers. One need only imagine how forthcoming a public official, corporate officer, or Klansman is apt to be after he is warned in writing by a historian or political scientist about the legal, economic, emotional, and reputational risks of participating in an interview.⁸⁴ Informed consent thus is as dangerous a mode of licensing as IRBs. Although the consent ultimately comes from the individuals with whom the researcher hopes to communicate, it is another level of licensing, in which the researcher is forced to get prior permission not merely from the IRB but also from any member of society to whom he wishes to speak or submit questions.

This democratized licensing may seem salutary. Certainly, as a means of avoiding a battery, consent is an elegant method by which a doctor or a researcher can avoid some types of liability and some ethical problems. Where a doctor has a fiduciary duty to a patient, moreover, he has a duty to supply the patient with enough information to make a decision in his best interest. It is no coincidence, however, that doctors judge for themselves

⁸⁴ These examples are hardly gratuitous—two of them being close to the author’s own research.

the amount and sort of information they should give their patients.⁸⁵ Nor is it an accident that doctors judge for themselves even whether to get informed consent, for only they are in a position to weigh their desire to protect themselves against their judgment about the competence of their patient and how much information he can handle. At least among doctors who are not doing research, informed consent is not a system of licensing, and this is a reminder that even for purposes of informed consent, the government cannot constitutionally establish a system requiring individuals to get permission before speaking or printing.

In fact, the democratized character of the licensing in the Common Rule's informed consent requirement illustrates how completely IRBs consolidate centralized legal force and local social force. In a republic, where government is responsive to the concerns of the people, the government's imposition of licensing is likely to threaten individual authority with the combined force of government and popular opinion; and certainly after popular anxieties about research led to the adoption of the Common Rule, the government not only required researchers who studied human subjects to get permission from IRBs but also required them to get signed permission from those whom they studied—even if only to observe them in public or to talk to them about politics.⁸⁶ In this democratized manner, everyone became a licenser with the power to stop an academic from asking troublesome questions, and the law thus requires researchers to get layers of federal and social permission—initially from the IRB, which is expected to enforce both federal and “community” standards, and then from the human subjects, who impose their own, individual versions of the communal standards.⁸⁷ Informed consent thus completes the gauntlet of national, local, and personal permission.

In sum, the IRB laws regulate research by imposing licensing on speech and the press. The Common Rule directly imposes IRB licensing on the pursuit of “generalizable knowledge”—knowledge that can be “expressed” in general theories or statements—and as if this were not enough, it is widely recognized that this means licensing of what is designed to be “publish[ed].”⁸⁸ Under the authority of the Common Rule, IRBs regularly prevent individuals from asking or publishing about the identity of a human subject or whatever else the IRBs consider “sensitive” or offensive to “community standards.”⁸⁹ Reinforcing these conclusions about the direct imposition of licensing on speech and the press, the Common Rule singles

⁸⁵ Indeed, doctors are not clearly obliged to get informed consent for psychotherapy and other procedures not requiring contact. For psychotherapy, see THOMAS G. GUTHEIL & PAUL S. APPELBAUM, *CLINICAL HANDBOOK OF PSYCHIATRY AND THE LAW* 160 (2000).

⁸⁶ Along the same lines, IRBs are required to include at least one community member selected for his or her sensitivity to community sentiments.

⁸⁷ See text accompanying *supra* note 55.

⁸⁸ See *supra* notes 66–69.

⁸⁹ IRB GUIDEBOOK, *supra* note 49, at ch. III, pt. A.

out for licensing the research conducted by institutional researchers, which is like targeting the research done by investigative journalists. The Common Rule, moreover, is so overinclusive that it imposes licensing on entire fields in which inquiry consists of little more than the use of verbal language. Last but not least, the Common Rule requires informed consent of a sort in which not only IRBs but also individuals act as licensors—even merely as to conversation. The Common Rule thus clearly imposes licensing on speech and the press, and this leads to the next question: whether the government imposes this licensing with the obligation of law.

C. *The Obligation of Law*

Contrary to widespread assumptions, both the federal and state governments impose the IRB licensing with the obligation of law, and by bringing the force of their laws to bear on behalf of the licensing, they collide with the federal and state guarantees of freedom of speech and the press.⁹⁰ Proponents of IRBs tend to assume that the IRB system is constitutional because it is merely a condition of federal research grants.⁹¹ This, however, is another of the casual assumptions that has given legitimacy to the system of licensing. In fact, both the federal government and the states have given the licensing the obligation of law.

1. *Conditions on Spending.*—The surface mechanism with which the federal government imposes the Common Rule on researchers is by making the use of IRBs under the Common Rule a condition of federal research grants. The federal government tends to emphasize this enforcement mechanism, for this method has at least the potential to appear lawful. Yet this use of conditional grants to establish IRBs goes far beyond ordinary spending conditions, and it is therefore probably unconstitutional even under the Supreme Court's rather amorphous doctrine of unconstitutional conditions. More to the point here, this use of conditions on spending illustrates how the Court's own doctrine on spending opened up an opportunity for Congress to evade the First Amendment. The Court's spending doctrine gave the IRB laws at least a superficial appearance of legitimacy, and although, in fact, the IRB laws probably run afoul of the Court's doctrine on spending and unconstitutional conditions, the role of the Court's spending doctrine in creating an end run around the First Amendment suggests that it is necessary to look beneath the Court's doctrines in search of such law as still can be discerned below. It is an argument that appears in more detail elsewhere, but even in summary form it should suffice to suggest why the

⁹⁰ For the remarkably casual, even cursory, constitutional arguments of the proponents of IRBs, see sources cited *supra* note 39.

⁹¹ See, e.g., *supra* note 39.

government's use of conditions to impose the IRB laws must be considered unconstitutional.⁹²

The mechanism by which IRBs become conditions on federal research grants appears at first glance to be perfectly constitutional. The federal government has no enumerated power over medicine, research, speech, or the press, and the First Amendment prohibits the government from abridging the freedom of speech or of the press.⁹³ The First Amendment's guarantee of speech and the press, however, does not limit the federal government's spending, including its granting of money or other privileges, and it is therefore often taken for granted that the federal government can require IRB licensing under the Common Rule as a condition of its grants for human subjects research. On such assumptions, as has been seen, the federal government channels its grants for such research through universities and other institutions, which are eligible for the grants only after giving the government an assurance that they will adhere to the Common Rule and thus will use IRBs for all federally supported human subjects research.⁹⁴

The federal government, however, has used its conditions to do much more than get assurances as to the research it funds. More ambitiously, it has used its funding of some human subjects research as leverage to get assurances of IRB licensing for all such research. To this end, it pressured institutions in the late twentieth century to give assurances that they would follow the Common Rule and thus use IRBs for all human subjects research, regardless of its source of funding. The government pressured institutions into giving this additional assurance in various ways: by not giving them any other option on the assurance form, by threatening institutions that their grants would be at risk, and, most forcefully, by holding up acceptance of assurances that only extended to federally funded research.⁹⁵ Not surprisingly, these pressures led most research institutions to assure the federal government that they would impose the Common Rule's IRB licensing on all human subjects research, including that which was without federal funding.⁹⁶

⁹² See Hamburger, *supra* note 6, at 314–27, 332–33.

⁹³ U.S. CONST. art. I; U.S. CONST. amend. I.

⁹⁴ 42 U.S.C. § 289 (2000); *see also* Hamburger, *supra* note 6, at 324.

⁹⁵ Hamburger, *supra* note 6, at 328–29. The AAUP has stated: “While the rule does not prescribe the content of a statement of principles, a university is plainly under considerable pressure from the government to apply its procedures to all human-subject research.” *Protecting Human Beings*, *supra* note 39, at 60.

⁹⁶ At one point, according to persons who were in a position to know, all but about five of the institutions that needed Multiple Project Assurances—the general, ongoing type of assurance necessary for any major research institution—assured OHRP that they would comply with the Common Rule in licensing of all human subjects research, not merely that which was funded by the government. Hamburger, *supra* note 6, at 329 n.137. As of the end of 2005, however, 164 institutions that have given an assurance about complying with the Common Rule have opted to provide this assurance only as to federally funded research. *Research on Human Subjects: Academic Freedom and the Institutional Review Board*, ACADEME, Sept.–Oct. 2006, at 95, 99. [hereinafter *AAUP Report II*]. The former number may

The federal government ordinarily need not worry about the speech and press guarantee of the First Amendment when it places limitations on its purchases, but it cannot so clearly escape the First Amendment when it uses conditions on its spending as a means of regulation. Under traditional understandings of the First Amendment speech and press guarantee, conditional spending is not unconstitutional, because it is not an abridgment of freedom. Yet when the spending becomes, in reality, an instrument of regulation or constraint, then the courts should recognize the reality that Congress may be using its power to spend to get around the constitutional limits on its power to regulate.⁹⁷

The Supreme Court has not elaborated its doctrine of unconstitutional conditions with any clarity, but the Court's expansion of federal power—especially its acknowledgment of a federal spending power—gives the task particular urgency. The First Amendment bars laws abridging or constraining the freedom of speech or the press, and Congress therefore long used its traditional enumerated powers, such as its power “[t]o raise and support armies,” to purchase what it needed without fear of running afoul of the First Amendment guarantee of freedom of speech and the press.⁹⁸ Increasingly, however, Congress spends with few limitations, for the Supreme Court has legitimized a general Congressional spending power. In the 1780s, Gouverneur Morris and some others hoped that the Constitution would give the federal government a general spending power, but the Constitutional Convention emphatically rejected this position and drafted the Constitution to make clear that Congress could only spend through its enumerated powers and that these did not include a general power to spend.⁹⁹

have been disseminated by the government to discourage institutions from opting out. More certainly, the government since December 2000 has made clear to institutions that they can opt out. *See infra* note 108 and accompanying text. Of course, none of this means that the institutions can escape the ethical principles condition. Nor, as will become apparent, does it mean that they can avoid using IRBs for human subjects research not funded by the government. It does not even mean that they ordinarily can avoid using IRBs that meet the standards of the Common Rule for such research. Instead, it only means that they have not assured the government they will comply with the Common Rule for the research not funded by the government, and this spares them the duty to report violations in such research. *See infra* note 108 and accompanying text.

⁹⁷ This theory as to how the doctrine ideally should be understood is laid out in Hamburger, *supra* note 6, at 314–21, which draws the distinction between purchase and regulation from Lynn Baker, *Conditional Federal Spending After Lopez*, 95 COLUM. L. REV. 1911, 1962–78 (1995). This sort of unconstitutional conditions issue obviously can be distinguished from the equal protection style equality or public forum questions, which arise when government allocates access to public property or common space.

⁹⁸ U.S. CONST. art. I, § 8.

⁹⁹ The first paragraph of Section 8 of Article I grants a single power, in which the allusion to spending is only a limitation on the power to tax. This conclusion, although no longer widely recognized, is evident from the text: “The Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defense and general Welfare of the United States; but all Duties, Imposts and Excises shall be uniform throughout the United States . . .” *Id.* art. I, § 8, cl. 1. There might have been a spending power here if there had been a semi-colon or the word

Nonetheless, in the twentieth century, the Supreme Court acknowledged a general spending power, and Congress uses this power not merely to purchase goods and services but also to impose regulation.¹⁰⁰

This matters for IRBs because when the spending is really a means of imposing regulation, and when this regulation violates the First Amendment, the courts should recognize the Congressional overreaching, and should hold it unconstitutional. It once might have been plausible for the Supreme Court to assume that it should not delve into questions about what purchases really are regulations, for when the Bill of Rights was adopted, it was clear that the Congress could spend through its enumerated powers, and yet the Bill of Rights did not in most clauses bother to limit more than legal constraints—what the First Amendment, for example, calls laws “abridging” the freedom of speech or the press. Now, however, the Supreme Court has given Congress a general spending power—not to mention other expanded powers—and if the Supreme Court thus can expand Congressional power in a way that allows Congress to make an end run around much of the Bill of Rights, then the Court also has the power and the duty

“and” after the word “Excises,” and therefore to find a general spending power here is to assume that the Constitution inadvertently has a comma where it was meant to have a semi-colon or conjunction.

As it happens, it is unusually clear that this comma was not intended to be anything else. The history of the spending power is recounted in Jeffrey T. Renz, *What Spending Clause? (Or the President's Paramour): An Examination of the Views of Hamilton, Madison, and Story on Article I, Section 8, Clause 1 of the United States Constitution*, 33 J. MARSHALL L. REV. 81 (1999). Although he notes it only in passing, there was a surreptitious attempt to create a separate spending power by adding a semi-colon after the word “Excise.” *Id.* at 105. On September 4, 1787, the Committee of Eleven reported to the Convention a draft of what became Section 8, which read: “The Legislature shall have power to lay and collect taxes, duties, imposts, and excises, to pay the debts and provide for the common defense and general welfare of the United States.” 2 RECORDS OF THE FEDERAL CONVENTION 493 (Max Farrand ed., 1911) [hereinafter 2 RECORDS] (Journal, Sept. 4, 1787). On September 12, the Committee on Style reported a version of this paragraph, and the next day it distributed a printed version of its report. 3 RECORDS OF THE FEDERAL CONVENTION app. a, cccxlv at 457 (Max Farrand ed., 1911) (memoirs of John Quincy Adams). In this printed report, however, there was not a comma, but a semi-colon after the word “excises”—so that “to pay the debts and provide for the common defence and general welfare of the United States” became an additional power, conjoined to the power to tax, rather than merely a limitation on it. 2 RECORDS, *supra*, at 594 (Report, Sept. 12, 1787). The Convention, however, recognized this alteration and rejected it. At stake was simply the addition and removal of a single dot above a comma. Rarely has so much rested on so small a point.

Its importance was recognized in early debates about the Constitution. For example, in 1798, Albert Gallatin told the House of Representatives

he was well informed that those words had originally been inserted in the Constitution as a limitation to the power of laying taxes. After the limitation had been agreed to, and the Constitution was completed, a member of the Convention, (he was one of the members who represented the State of Pennsylvania [*i.e.*, Gouverneur Morris]) being one of a committee of revisal and arrangement, attempted to throw these words into a distinct paragraph, so as to create not a limitation, but a distinct power. The trick, however, was discovered by a member from Connecticut, now deceased, and the words restored as they now stand.

3 RECORDS, *supra*, at app. a, cclxxxi at 379 (Albert Gallatin in the House of Representatives, June 19, 1798).

¹⁰⁰ United States v. Butler, 297 U.S. 1, 66 (1936); South Dakota v. Dole, 483 U.S. 203, 211 (1987).

to elaborate the limits of its expanded vision of Congressional power in a way that protects the Bill of Rights. In short, whatever one thinks in the abstract about a doctrine of unconstitutional conditions, the Court has expanded federal spending power in a way that facilitates evasion of the enumerated rights, and the Court therefore has a duty to confine this power to the extent necessary to protect these rights.¹⁰¹

The government's imposition of the IRB licensing system through conditions on government grants therefore does not clearly escape the First Amendment's guarantee of speech and the press. To be precise, although the federal government can place conditions on its purchases, it should not be able to use its grants to impose a system of regulation that abridges the freedom of speech and the press. It would be bad enough if the government merely took advantage of the large number of its grants to impose licensing of speech and the press on the research it supports, for even this would foist an unconstitutional form of regulation on a wide swath of academics. As it happens, however, the government has leveraged its grants to impose IRB licensing even on the research it does not support, and it thus all the more clearly is not merely limiting its purchases, but imposing regulation—in this instance, a regulation that unconstitutionally controls research by licensing speech and the press.

Lest the unconstitutionality be unclear, consider once again the example of Newspaper Review Boards; but this time imagine that the government systematically funded newspapers on the condition that journalists get permission from NRBs before beginning their investigations. The government would argue that it sought the NRB licensing simply as a condition of its grants. Yet even if the government sought NRB licensing only for the journalistic investigations it funded, its conditions would justifiably be considered unconstitutional if it used the sheer number of its grants to transform its spending into a means of regulation—if it spread its funding around in a way that gave its purchases a regulatory effect. If, moreover, the government leveraged its funding of some investigative journalism to impose NRB licensing on all investigative journalism, it would all the more clearly be using its spending, in reality, as a mode of regulation—a regulation that would violate the First Amendment.¹⁰² Thus, as illustrated by

¹⁰¹ The emphasis here is on the spending power, as this is the power that advocates of IRBs tend to rely upon. Obviously, however, the argument here applies to any expanded Congressional power to spend—for example, under an expanded commerce clause power.

For purposes of discerning when mere spending amounts, in reality, to the obligation of law, it is important to remember that what matters is not any punishment or coercion, but merely the obligation of law. For example, even if a statute imposed no fine, imprisonment, or other penalty, it would be unconstitutional if it required licensing of newspaper articles.

¹⁰² In *Stanford v. Sullivan*, a U.S. district court even held a single condition in a single research grant unconstitutional because it required the researchers to get permission before publicly discussing their results; otherwise, “the result would be an invitation to government censorship wherever public

NRBs, it is necessary to examine the government's spending on research—spending that is tied to the use of IRBs—to determine whether, in reality, it is regulatory. Otherwise, the federal government would be able to use its Court-created spending power to purchase its way around most of the Bill of Rights.

The Supreme Court has yet to clarify the constitutional limitations on spending, but it has noted that although Congress has a spending power, “other constitutional provisions may provide an independent bar to the conditional grant of federal funds.” In *South Dakota v. Dole*, the Court denied that this “‘independent bar limitation’” is “a prohibition on the indirect achievement of objectives which Congress is not empowered to achieve directly.”¹⁰³ More recently, however, in *United States v. American Library Association, Inc.* and *Rumsfeld v. F.A.I.R.*, the Court has said that “the government may not deny a benefit to a person on a basis that infringes his constitutionally protected . . . freedom of speech even if he has no entitlement to that benefit”—a point that the Court in *Rumsfeld* expounds as to universities.¹⁰⁴ The Court thus occasionally reveals at least a vague understanding of the underlying problem.

The Supreme Court's doctrines gave legitimacy to the government's use of spending as a means of regulation, and the Court therefore is largely responsible for the peril that the government can use such spending to evade almost all constitutional limits, including the Bill of Rights. The Court thereby has left academics to suffer for three decades under a massive, seventeenth-century style system of licensing. Accordingly, even if the government's use of spending to impose regulation were not ordinarily subject to the freedom of speech and the press, the Court that created a federal spending power has an obligation to prevent this power from being used to sidestep the First Amendment.

2. *Negligence Law.*—The obligation of law behind IRBs is not limited to conditions on government grants, for the federal government also co-opts state negligence law. The federal government has carefully inculcated the impression that IRB licensing is the professional standard for research,

funds flow, and . . . thus . . . an enormous threat to the First Amendment rights of American citizens and to a free society.” 773 F. Supp. 472, 478 (D.D.C. 1991).

¹⁰³ 483 U.S. at 210. At the same time, the Court said that:

[W]e think that the language in our earlier opinions stands for the unexceptionable proposition that the power may not be used to induce the States to engage in activities that would themselves be unconstitutional. Thus, for example, a grant of federal funds conditioned on invidiously discriminatory state action or the infliction of cruel and unusual punishment would be an illegitimate exercise of the Congress' broad spending power.

Id. at 210. To this, one might add that a grant of federal funds conditioned on the licensing of speech or the press by a state university also would be unconstitutional.

¹⁰⁴ *Rumsfeld v. F.A.I.R.*, 126 S. Ct. 1297, 1307 (2006); *United States v. Am. Library Ass'n*, 539 U.S. 194, 210 (2003) (quoting *Bd. of Cmms'rs, Wabaunsee Cty. v. Umbehr*, 513 U.S. 668, 674 (1996)) (internal quotation marks omitted).

and it has thereby brought the obligation of state tort law to bear on institutions that fail to adopt IRB licensing. Thus, even if an institution only gives an assurance that it will use IRB licensing for federally funded research, the institution still must worry about civil judgments under state negligence law if it fails to apply the licensing to all human subjects research.¹⁰⁵

An early hint of the potential for relying on the force of negligence law came in 1978 from the National Commission for the Protection of Human Subjects. According to the Commission's *Report and Recommendations*, "[i]n negligence *per se* jurisdictions, violation of IRB rules could be taken as evidence of negligence," and "[i]n other jurisdictions, the widespread use of IRBs in the research community may create a standard of care for the conduct of all research."¹⁰⁶ In other words, if the federal government could use its funding to make the use of IRBs widespread, it gradually could establish the use of IRBs as the standard of care for all research, even if not funded by the federal government. Although the Commission's immediate focus was the liability of researchers who fail to get permission from an IRB, the risk of liability obviously would also fall on any institution that failed to impose IRBs on human subjects research, regardless of the source of funding, and this was the implication that would become particularly significant.¹⁰⁷

So successful was the federal government in elevating IRB licensing as the standard of care that it eventually was able to switch from relying on conditions on grants to relying on state negligence law. The federal government in the late twentieth century pressured institutions to assure the government that they would apply the Common Rule to all human subjects research, even if not federally funded, but by 2000, the government's conditions on its grants had made IRB licensing the accepted standard of care for purposes of negligence. Negligence law even seemed to require IRB licensing in conformity with the Common Rule. The government could therefore afford to relax its efforts. Accordingly, it altered its assurance form to make clear that for research without federal funding, the assurance about complying with the Common Rule was merely "[o]ptional."¹⁰⁸ Some institutions

¹⁰⁵ Some states also use statutes to give legal obligation to the IRB laws. These statutes deserve careful study, for they directly require researchers to get permission from IRBs, and their requirements will probably be of growing significance. They are not a focus of this inquiry, however, because they are not uniform and have not been adopted in many states, and thus, unlike state negligence law, they are not currently central to the overall structure of the IRB laws.

¹⁰⁶ See NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, DHEW PUBLICATION NO. (OS) 78-0008, REPORT AND RECOMMENDATIONS: INSTITUTIONAL REVIEW BOARDS 86 (1978).

¹⁰⁷ See *id.*

¹⁰⁸ Office of Human Research Prots., U.S. Dep't of Health Human Servs., Step-by-Step Instructions for Filing a Federalwide Assurance for Institutions Within the United States, Item 4(b) (June 6, 2005), <http://www.hhs.gov/ohrp/humansubjects/assurance/filasuri.htm>; see also Hamburger, *supra* note 6, at 329. The government, however, still exerts its power, and when institutions seek to avoid giving assurances as to non-federally funded research, they can be required to beef up their assurances with licensing

responded by dropping their assurances as to such research, but they of course continued to require IRBs for all human subjects research, regardless of its funding, lest they run afoul of what by now had become the standard of care.¹⁰⁹ In other words, the federal government only conceded that assurances as to non-federally funded research were “[o]ptional” when the use of IRBs no longer seemed optional under state tort law.¹¹⁰ Although the fed-

rules not required by the federal regulations—as when the government required the University of Chicago under its old assurance to provide an assurance that their researchers will not simply treat exempt research as exempt but will first ask their IRBs whether it really qualifies as exempt: “All human subject research which is exempt under Section 101(b)(1-6) or 101(i) will be conducted in accord with . . . this Institution’s administrative procedures to ensure valid claims of exemption.” Univ. of Chi., Multiple Project Assurance of Compliance with DHHS Regulations for Protection of Human Research Subjects, at pt. III.B (on file with author). For the significance of this, see *infra* text accompanying note 180.

¹⁰⁹ Apparently as of late 2005, there were 164 institutions that assured the HHS of their compliance with the Common Rule only for federally funded research. See *supra* note 96.

A 2001 AAUP report explains the difficulty of applying a lower standard of licensing for research that is not federally funded:

Consider the following: a privately funded research project is carried out at a university, one of the human subjects claims to have been harmed by the research, and the subject sues the university. Consider further that the university’s IRB does not review research that is not funded by the government. The litigant will almost certainly argue that the university’s failure to review privately funded research while it reviews government-funded research is proof that it acted unreasonably. Conversely, if the university’s IRB has approved the research, the university will cite that fact as evidence of its reasonableness in permitting the research to go forward. Whatever the merits of these arguments, the university’s legally prudent course of action, so the lawyers will advise, is for its policy to apply to all research on human subjects, irrespective of the source of funding. An aversion to legal risks may also help explain the actual decision of IRBs, to the extent that they seek to protect the institution (and perhaps themselves as well) from lawsuits that allege mistreatment of human research subjects.

The Report adds that “no university is likely to want to explain to either the government or the public why its commitment to avoid harming the human subjects of research is limited by the source of funding for the research. This prospect is even less attractive as IRBs expand their authority in response to concerns that the government must do more to protect human research subjects.” *Research on Human Subjects*, *supra* note 96, at 55, 60. On a related question, see Roger L. Jansson, *Researcher Liability for Negligence in Human Subject Research: Informed Consent and Researcher Malpractice Actions*, 78 WASH. L. REV. 229 (2003).

¹¹⁰ The courts have not had opportunities to make broad statements about IRBs and their licensing as the standard of care, because all universities now have IRBs, and universities appear to settle the suits brought against them for research that did not get IRB permission. Nonetheless, the role of the Common Rule as the standard of care is clear enough from the cases on informed consent. A presidential council reports:

Most courts addressing the question have held that the standards for informed consent set forth by the Common Rule and FDA’s human-subject protections constitute the relevant standard of care, the breach of which may be considered actionable. Two courts have gone farther: one holding that the researcher must disclose any conflicts of interest, and another holding that parents are legally incapable of subjecting their children to *any* risks in nontherapeutic research.

PRESIDENT’S COUNCIL ON BIOETHICS, REPRODUCTION AND RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES 116–17 (2004) (citing *Moore v. Regents of the University of California*, 793 P.2d 479, 486 (Cal. 1990); *Grimes v. Kennedy Krieger Institute, Inc.*, 782 A.2d 807, 846 (Md. 2001)).

One result is that “research institutions must increasingly take a conservative approach to granting licenses for social research because IRB approval is one criterion for determining whether the university is culpable, with the researcher for harm to subjects.” Lauren H. Seiler & James M. Murtha, *Federal*

eral government continues to require IRB licensing for federally funded research as a condition of its grants, it can now rely more substantially on state negligence law to get universities to license speech and the press as to all human subjects research, regardless of the source of its funding.

The federal government thus has co-opted the obligation of state negligence law to impose licensing, and the result is as unconstitutional as if the federal government had acted under federal law. Whether under state constitutions or under the First Amendment (as applied to the states through the Fourteenth Amendment), a state law inflicting civil penalties for not imposing a licensing system is subject, at the very least, to an emphatic presumption of unconstitutionality. Indeed, it should be considered utterly unconstitutional.

3. *Delegation.*—More, however, needs to be said, for might not the delegation of the licensing to universities and other institutions somehow insulate the licensing from constitutional critique? Put another way, is there not a distinction between a law requiring individuals to get licenses from the government and a law penalizing institutions that fail to impose the licensing on their personnel? The distinction matters, but in ways that may be unexpected.

Sociologically, the delegation allows the government to establish licensing of a sort that otherwise might not be possible in a free society. In such a society, government cannot easily license most speech or the press directly, for it is apt to have difficulty exerting enough control over the populace, and in particular it is vulnerable to resistance from independent institutions, such as universities. The government, however, can largely avoid this problem by delegating the licensing to the very institutions that might otherwise resist. This was the solution the English government adopted in the sixteenth and seventeenth centuries. For example, in a Star Chamber decree of 1637, the English government required officials of the church, the stationers company, and the universities to license books—the university and church officials having special jurisdiction over books “of Divinity, Phisicke, Philosophie, [and] Poetry.”¹¹¹ Similarly, in twentieth-

Regulation of Social Research: Is “Prior Review” Posing a Threat to Academic Freedom?, 53 FREEDOM AT ISSUE 26, 29 (1979). For example, when Columbia University was sued for the deceptive research conducted by a business school professor who never bothered to consult an IRB, the University dramatically increased the reach and severity of its IRB licensing so as to eliminate any laxity, even in fields such as law, which only engage in verbal research. The University warned: “Conducting human subjects research without appropriate training and review could have serious consequences.” E-mail from Alan Brinkley, Provost, & Executive Vice President for Research to Faculty, Administrators, and Students at Columbia University’s Morningside Campus (Oct. 15, 2004) (on file with author). OHRP itself uses the threat of liability to pressure IRBs to evaluate research methodologies: “Research that is conducted so poorly as to be invalid exposes subjects and the institution to unnecessary risk.” IRB GUIDEBOOK, *supra* note 49, at ch. I.B.

¹¹¹ A DECREE OF STARRE-CHAMBER, CONCERNING PRINTING § III, at B3 (July 11, 1637). For a similar provision later in the century, see An Act for Preventing the Frequent Abuses in Printing Sedi-

century America, the federal government could not simply require all individuals studying human subjects to submit to federal licensers. It could, however, force the universities to license their own personnel.¹¹²

Rather than escape constitutional scrutiny, this delegated licensing is squarely within the range of what the First Amendment forbade. Delegation, not least to the universities, was a prominent element of seventeenth-century English licensing, and because this English licensing was the primary model of what the First Amendment most clearly prohibited, the delegation of licensing to IRBs actually confirms the unconstitutionality of the present day licensing laws. Of course, government mechanisms for getting cooperation have changed, and whereas government in the seventeenth century relied on Star Chamber decrees and acts of Parliament to get the universities and other institutions to participate, it must now evade the First Amendment and therefore must rely on unconstitutional conditions and state negligence law. Nonetheless, government again is in the business of requiring universities to license academic work, and rather than confine itself, as in the past, to requiring the universities to license printing, government now additionally requires them to license any pursuit of generalizable knowledge—even if merely by talking, writing, observing, recording, and publishing.

To make matters worse, the delegation, as in the seventeenth century, subjects individuals to layers of central and local standards. Although it is well known that licensing standards tend to be vague, delegated licensing allows an array of vague standards, and the federal government has taken full advantage of this opportunity. The federal government explains that its standards for IRBs only are a minimum and that IRBs are free to enforce

tious, Treasonable, and Unlicensed Books and Pamphlets, 14 Car. II, c. 33, § 2 (1662). For a history of the legal mechanisms the English government used to control the press in the sixteenth and seventeenth centuries, see generally Hamburger, *supra* note 15, at 661 (1985) (providing an analysis of the different options available to the government for controlling printing).

¹¹² Delegation is not the only way in which the modern licensing echoes that of the past. For the religious element, see *supra* note 60 and *infra* note 148. In addition, just as the English government in the seventeenth century relied on the Stationers Company to ensure that imprimaturs appeared at the front of books, the government today can rely on the editors of academic journals to refuse to publish articles in which the authors do not state that their research had IRB permission. See Hamburger, *supra* note 6, at 303–04. Even more insidious is the education program. The English government in the seventeenth century attempted with considerable success to persuade academics and printers that licensing served the public good, and similarly today, the federal government engages in a large scale education project to induce cooperation—the effect being to make academics believe that they should accept the censorship. It may have been in these educational programs that the government popularized the slogan, “Research is a privilege, not a right.” Certainly, as noted by Richard O’Brien, the notion that research is a privilege turns up in one of the government’s educational films from the mid-1980s. Richard M. O’Brien, *The Institutional Review Board Problem: Where It Came From and What to Do About It*, 15 J. SOCIAL DISTRESS AND THE HOMELESS 23, 33 (2006). For more about this astonishing slogan, see Hamburger, *supra* note 6, at 353.

additional local standards that reflect “community” values.¹¹³ Although this appears to leave some freedom for institutional variation, it becomes a mechanism for IRBs to act under the color of federal and state law in imposing local prejudices that further restrict individual freedom.¹¹⁴ The Common Rule even requires that at least one IRB member be a community member and that all IRB members be chosen for their “sensitivity to . . . community attitudes.”¹¹⁵ On some IRBs, this is conveniently taken to mean the inclusion of local policemen or at least individuals who feel confident they can call on the police to assist in enforcement.¹¹⁶ Like a local sheriff wearing a federal badge, IRBs thus swagger with all the pretensions of federal power and all of the petty oppression of local bullies.¹¹⁷ Jack Katz

¹¹³ The Common Rule defines “IRB approval” as “the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.” 45 C.F.R. § 46.102(h) (2005). Thus, as explained by OHRP, an IRB must make “a judgment that often depends upon prevailing community standards and subjective determinations of risk and benefit. Consequently, different IRBs may arrive at different assessments of a particular risk/benefit ratio.” IRB GUIDEBOOK, *supra* note 49, at ch. III.A. Much research has established the variability of IRB determinations. See, e.g., Jon Mark Hirshon et al., *Variability in Institutional Review Board Assessment of Minimal-Risk Research*, 9 ACAD. EMERGENCY MED. 1417 (2002); Thomas O. Stair et al., *Variation in Institutional Review Board Responses to a Standard Protocol for a Multicenter Clinical Trial*, 8 ACAD. EMERGENCY MED. 636 (2001); Mary Terrell White & Jennifer Gamm, *Informed Consent for Research on Stored Blood and Tissue Samples: A Survey of Institutional Review Board Practices*, 9 ACCOUNTABILITY IN RES. 1 (2002).

¹¹⁴ IRB GUIDEBOOK, *supra* note 49, at ch. III, pt. A.

¹¹⁵ Each IRB, according to the Common Rule, is required to

be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

45 C.F.R. § 46.107(a) (2005). To this end, at least one member of each IRB must be unaffiliated with the institution that established the IRB, and this member is expected to stand up for the “perspective” of the “local community.” IRB GUIDEBOOK, *supra* note 49, at ch. I, pt. B. For this membership requirement, see 45 C.F.R. § 46.107(d). Community members even form a majority of the members of at least one leading university’s IRB.

¹¹⁶ The most prominent of the various academic institutions known to have included a police officer is Northwestern University. Although on the IRB roster (for panel E) he is described simply as being associated with the University’s Center for Public Safety, he is its director, which is an anodyne way of saying he is the chief of the Northwestern police department. See Northwestern University Office for Research, Institutional Review Board Members, <http://www.research.northwestern.edu/research/oprs/irb/boardMembers/> (follow “Panel E Members” hyperlink) (last visited Nov. 17, 2006). In addition to the IRBs that include police officers, there are IRBs that assume they can rely on the police. When David Wright—an African American professor of English at University of Illinois, Champaign-Urbana—wrote a literary essay and got it accepted for publication, “the IRB chair threatened to prevent publication of the article if Wright didn’t withdraw it from the *Kenyon Review*, and even to contact the police.” E-mail from Dennis Baron to Philip Hamburger (Oct. 20, 2004) (on file with the author). Baron was then the Chair of the English Department. For further details of the incident, see David Wright, *Creative Nonfiction and the Academy: A Cautionary Tale*, 10 QUALITATIVE INQUIRY 202 (2004); Hamburger, *supra* note 6, at 303.

¹¹⁷ For an earlier use of the sheriff metaphor, see Thomas A. Huff, *The IRB as Deputy Sheriff: Proposed FDA Regulation of the Institutional Review Board*, 27 CLINICAL RES. 103 (1979).

documents that IRBs have repeatedly imposed their local political prejudices on researchers, and they can do so all the more successfully precisely because they enforce local moral prejudices with the authority of law—indeed, both state and federal law.¹¹⁸ The combination of legal force and local prejudice was bad enough in the West in the nineteenth century, and although the bureaucratic version of this combination in modern universities is less violent, it is no less stifling.

The Supreme Court has given hints that it recognizes the danger that the federal government will use its funding and other mechanisms to delegate regulation that the government itself could not constitutionally impose. In *Rust v. Sullivan*, family planning agencies accepted federal funding on the condition that the doctors who worked for them would not counsel abortions.¹¹⁹ The Supreme Court upheld this condition but at the same time suggested it would not have sustained such a condition on employees where they were acting independently of the funded institutions—the preeminent example being the independence of academics from their universities.¹²⁰ The Court's position cannot be taken to mean that academics have greater constitutional freedom than other Americans. Rather, for long standing cultural reasons, the faculty and students of academic institutions are presumed to be independent of their institutions within the sphere of their academic freedom, at least in the absence of clear contractual provisions to the contrary.¹²¹ Thus, whereas the doctors in *Rust v. Sullivan* were presumed to be agents of their employers when acting for them, professors and students cannot be presumed to be agents of their institutions while within the realm of their academic freedom, including their research. Accordingly, although the government can use conditions on funding to limit the messages it purchases from family planning agencies, it cannot use conditions on its funding of academic institutions to limit what is said or printed by students and faculty, for on account of the independence of these individuals, the conditions would amount to a delegated regulation, and being a regulation abridging the freedom of speech and the press, it would be unconstitutional. How much of this the Court in *Rust* really understood is unclear, but the Court recognized enough to observe that “the university is a traditional sphere of free expression so fundamental to the functioning of our society that the Government's ability to control speech within that sphere by means of conditions attached to the expenditure of Government funds is restricted by the vagueness and overbreadth doctrines of the First Amendment.”¹²²

¹¹⁸ Jack Katz, Address at the Northwestern University School of Law Symposium: Censorship and Institutional Review Boards (Apr. 7, 2006). For other examples, see *Research on Human Subjects*, *supra* note 96, at pt. I.

¹¹⁹ 500 U.S. 173 (1991).

¹²⁰ *Id.* at 200.

¹²¹ Hamburger, *supra* note 6, at 341 n.162.

¹²² 500 U.S. at 200. The Court has frequently made such statements about the distinctive freedom enjoyed in universities, most recently in *Grutter v. Bollinger*, 539 U.S. 306, 329 (2003).

One need only add that this misuse of conditions is all the more emphatically restricted by the Amendment's prohibition against licensing.

Delegation thus does not excuse, but rather clarifies the constitutional problem. The delegation of licensing to universities invites local prejudice and is part of what the First Amendment historically forbade. Moreover, when the federal government uses conditions on its spending to get universities to license their personnel, it is all the more clearly using its spending power as a means of regulating the individuals, thus obtaining through surrogates the sort of regulation it cannot impose directly. Far from insulating government, the devolution of the licensing to surrogates confirms that in pressuring universities with conditions and legal liability, government is making them instruments for imposing regulation—in this instance, an unconstitutional kind of regulation, the licensing of speech and the press.

To summarize, the IRB laws directly require a system of licensing speech and the press, and nothing is more clearly or emphatically forbidden by the First Amendment's guarantee of freedom of speech and the press. Licensing is very different from other methods of controlling speech or the press because it requires individuals to get permission, and in thus undermining the authority of individuals in their use of language, it inverts the authority of the people in their relation to government. Such licensing therefore deserves the First Amendment's unequivocal prohibition, and the government's imposition of IRBs is a sad reminder of what is apt to happen when the absolute character of this barrier is forgotten. By lowering the barriers against licensing and spending, the Supreme Court inadvertently created an opening for the licensing of speech and the press, and the government therefore felt free to introduce a system of licensing unparalleled in England or America since the seventeenth century.¹²³ Nonetheless, even under the Constitution's diminished prohibition against licensing—what the Court treats as a mere presumption—it is difficult to discern a justification for the IRB laws, as will now become apparent.

III. FIDUCIARY DUTY

The IRB laws are sometimes justified as the means of enforcing a fiduciary duty. Just as doctors owe their patients a Hippocratic duty, so researchers, it is said, owe their human subjects an equivalent duty.

Yet far from being a government interest that could overwhelm the constitutional prohibition (or at least presumption) against licensing of speech or the press, the attribution of a fiduciary duty to researchers, as if they were professionals, only confirms the constitutional problem. Researchers are not professionals, and the government attributes a fiduciary duty to them as a class on account of their attempt to produce "generaliz-

¹²³ For the way in which the Supreme Court's doctrines on licensing and spending gave the federal government confidence it could impose IRBs and deprived academics of any confidence they could resist, see Hamburger, *supra* note 6, at 277–81, 351–54.

able knowledge.” To make matters worse, the particular duties attributed to researchers under the IRB laws are imperfect duties, which go far beyond what doctors owe their patients, and which are not of a sort normally considered compatible with the freedom of speech or the press. In the end, therefore, far from justifying the IRB laws, the claim about a fiduciary duty reveals that the IRB laws encounter constitutional problems not only on account of their method, licensing, but also on account of the substantive duties they impose.

Rather than coincidental, this danger from the substantive duties imposed by IRBs illustrates a risk that is apt to arise in any system of licensing speech or the press. A system of licensing, as is well known, can function without a clearly stated substantive standard.¹²⁴ Accordingly, by relying on a licensing system, such as that established by the IRB laws, government can surreptitiously impose heightened substantive duties, even imperfect duties, that otherwise would encounter political and constitutional obstacles.

A. *The Fiduciary Duty of Researchers*

The federal government uses IRBs to impose a fiduciary duty on researchers in relation to their human subjects—as if researchers were like doctors in relation to their patients. It is doubtful, however, whether a fiduciary duty can be imposed on a class on account of their desire for “generalizable knowledge.”

The fiduciary duties of professionals, such as doctors and lawyers, arose from the historic practice of these persons to sell the use of their judgment, speech, and conduct, which they voluntarily undertook to use on behalf of their clients. Physicians and lawyers thus became members of discrete professions, with their own group standards about the ways in which they should, almost literally, use parts of themselves—their minds, tongues, and hands—for those whom they assisted. Today, the fiduciary duty of a professional remains a duty to act on behalf of another, and it still arises from the professional’s voluntary undertaking—prototypically in exchange for money—to exercise his judgment, speech, or conduct on behalf of his client.

Researchers, in contrast, act for themselves rather than those they study, and they thus are generally free to act on their own, without being members of a professional group. Many of them could seek professional salaries by undertaking professional, fiduciary duties—in particular, by selling their professional judgment, speech, and conduct to their clients. Instead, they keep their freedom to think, speak, and act to their own satisfaction, and this is a freedom not merely from a fiduciary duty to a cli-

¹²⁴ See Thomas I. Emerson, *The Doctrine of Prior Restraint*, 20 LAW & CONTEMP. PROBS. 648, 655 (1955).

ent, but also from any professional duty to a group whose professional standards define the sort of judgment, speech, and conduct that can be sold by its members. Although academic organizations sometimes attempt to enunciate professional standards, they do so without any binding hold on scholars or on students, and dissenting academics and students thus remain entirely free to take their own approaches to research. In sum, academics and students generally act for themselves as individuals rather than for others as part of a profession.

Nonetheless, by means of IRBs, the federal government imposes a previously absent researchers' duty on students, academics, and other personnel at research institutions. This federal fiduciary duty is convenient for the federal government in managing its research grants, but it is ominous for researchers. Even for academic doctors and lawyers who do research on human subjects, the duty of researchers is a penalty on research, for it gives them a fiduciary duty to persons who are not their patients or clients. More broadly, it penalizes all sorts of scientists and humanists who never have had clients, but who study human subjects—whether in the lab or in the library—and thus get penalized on account of their curiosity, on account of their desire for “generalizable knowledge.”

The central events that seemed to justify holding human subjects researchers accountable in this manner have become notorious under the names of Nuremberg and Tuskegee. At Nuremberg, the Allies in World War II tried the doctors who had performed hideous experiments on their prisoners in concentration camps. At Tuskegee, the Public Health Service conducted a study that became symbolic of the idea that American doctors had equal potential for evil. The Nazi tortures and the American study obviously were very different, and it is by no means clear how either explains the necessity for licensing rather than after-the-fact penalties. Nonetheless, Nuremberg and Tuskegee are often mentioned in the same breath as proof that IRBs are necessary to prevent researchers from harming their human subjects.

The study at Tuskegee deserves particular attention because it illustrates the very real dangers of research in American society, and because the federal government, in its attempt to justify its imposition of a fiduciary duty on researchers, ended up misrepresenting what happened at Tuskegee. Beginning in the early 1930s, the federal government's Public Health Service attempted to study the course of untreated syphilis in black men in Macon County, Alabama—who had an unusually high rate of infection.¹²⁵ The researchers apparently screened out men who had been infected relatively recently and who thus had a good chance of benefiting from the contemporary treatment (with rather toxic arsenical injections). The

¹²⁵ Thomas Benedek, *The “Tuskegee Study” of Syphilis: Analysis of Moral Versus Methodologic Aspects*, in *TUSKEGEE'S TRUTHS: RETHINKING THE TUSKEGEE SYPHILIS STUDY* 213, 218–19 (Susan M. Reverby ed., 2000).

researchers then tracked the other men to study the development of their syphilis.¹²⁶ Although the researchers were doing research, they held themselves out to be providing at least some medical care: They were physicians who worked for the Public Health Service, they relied on a nurse to conduct follow up examinations, and they induced the men to participate by offering them checkups.¹²⁷ Penicillin became generally available for civilians after World War II, but notwithstanding that it had come to be recognized as a more effective cure for syphilis than arsenical injections, the researchers did not give the infected men penicillin. Nor did they inform them that penicillin might be of help. By the time penicillin became available, most of the men probably were beyond the benefits of the drug and were no longer contagious. Even so, penicillin probably could have helped at least some of them, but the doctors apparently reasoned that access to penicillin would have undermined the value of the study.¹²⁸ The details of the Tuskegee study became widely known in 1972 through an article in the *New York Times*, and ever since, the study has been the most notorious illustration of the physical and moral dangers of human subjects research.

More than research, however, occurred at Tuskegee. What happened there involved a breach of a fiduciary duty, for the study was carried out largely under the guise of offering medical care. Tellingly, not only the Tuskegee study, but also many other notorious twentieth-century studies (such as some of the military's radiological tests and the hepatitis study at Willowbrook) involved a combination of health care providers and government.

Even the standard academic article cited for the dangers of human subjects research—Henry Beecher's famous 1966 article—turns out to concern mostly medical research by doctors on patients in government institutions. Beecher purported to publish 22 cases of unethical “[h]uman experimentation,” but he frankly limited his study to research by doctors on their patients.¹²⁹ Although he did not say as much, his evidence also pointed to government. Three of the experiments examined by Beecher were done in England or the Philippines and therefore cannot be taken as evidence of American research.¹³⁰ Of the 19 remaining, American cases, at least 14 appear to have included patients in government institutions, ranging from the

¹²⁶ According to the first director of the study, “we treated practically all of the patients with early manifestations and many of the patients with latent syphilis.” *Id.* at 220.

¹²⁷ *Id.* at 221, 225.

¹²⁸ According to Benedek, “[t]he available treatment might have exerted a definitely beneficial effect on the prognosis of only 12.5% of the subjects.” *Id.* at 232. As it happens, “virtually all subjects who were alive in 1973 had outlived the life expectancy of their non-syphilitic peers[.]” *Id.* at 229.

¹²⁹ Henry K. Beecher, *Ethics and Clinical Research*, 274 *NEW ENG. J. MED.* 1354 (1966).

¹³⁰ For a list of the 22 experiments, with citations, see DAVID J. ROTHMAN, *STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW AND BIOETHICS TRANSFORMED MEDICAL DECISION MAKING*, 263–65 (1991). An examination of the published articles reveals that two of the cases, Beecher's numbers 15 and 19, were English. In addition, number 3 turns out to be a Filipino study.

Army to public hospitals or clinics, such as those at NIH. As might be expected, many of the doctors in these 14 cases were public employees or had public funding.¹³¹

Thus, the preeminent exemplars of unethical human subjects research tended to show not a single problem with human subjects research as a whole, but rather two narrower, overlapping problems. One problem centered on the research conducted in government institutions or under the authority of government; the other arose in research done by doctors on persons who had reason to think they were patients. This concentration of the most egregious instances of misconduct should not, perhaps, be a surprise, for government is sheltered from market and legal pressures, and doctors have difficulty studying their own patients without running up against a severe fiduciary duty that does not burden other researchers. Of course, there were misfortunes in research that did not involve government or doctors, and of course research in general has its risks, but the most sobering examples of research misconduct seemed to center on government and doctors.¹³² Indeed, in the preeminent examples—ranging from Nuremberg and Tuskegee to the cases studied by Beecher—the two areas of difficulty overlapped. Doctors acting under government authority or studying individuals within the care of government failed to live up to the duties that might ordinarily be expected of such professionals or as to such dependents.

The attempt to establish a fiduciary duty for human subjects researchers took its most concrete form in the late 1970s in the *Belmont Report*.¹³³ Produced by a national commission, this report is the central statement of the fiduciary duty that IRBs impose on human subjects researchers. When an institution seeks to qualify for federal funding, the government asks the institution to provide an assurance “that all of its activities related to human

¹³¹ These were cases numbers 1, 2, 4, 5, 7, 8, 10, 11, 12, 13, 14, 16, 20, and 22. See Rothman, *supra* note 130, at 263–65. (In at least three of these cases—numbers 4, 8, and 13—not all of the patients were in public institutions.) Rothman focuses on the capacity of the patients for informed consent and observes: “In almost all of the 22 protocols, the subjects were institutionalized or in some other situation that compromised their ability to give free consent.” David J. Rothman, *Ethics and Human Experimentation: Henry Beecher Revisited*, 317 NEW ENG. J. MED. 1195, 1198 (1987).

Beecher presumably omitted citations to his 22 cases to protect the researchers, who were *his* human subjects, but he thereby left his readers ignorant of essential data that, if published, would have revealed the degree to which his evidence did not clearly support his thesis. Like the suppression of data by IRBs, this sort of omission of personal details, which precludes replication, is simply incompatible with the serious conduct of scientific inquiry, and in this instance it has given supposedly scientific legitimacy to three decades of licensing.

¹³² After examining the usual complaints about the dangers of researchers, Richard O’Brien notes: “Closer analysis shows that government researchers have been responsible for almost all of the abuse of human subjects. . . . Logically, these data could only be used to support a human subjects protection program that had academic[s] . . . doing prior review of all government research not the other way around.” Of course, however, “[t]his obvious conclusion did not stop government regulators.” O’Brien, *supra* note 112, at 26.

¹³³ BELMONT REPORT, *supra* note 65.

subjects research, regardless of the source of support, will be guided by the ethical principles in the . . . Belmont Report.”¹³⁴ An institution can propose another statement of ethical principles, but apparently few institutions have tried this, for they recognize that the *Belmont Report* is the government’s preferred standard for research.¹³⁵ Accordingly, when the government presses universities to maintain the severity of their licensing, it almost always can refer to the *Belmont Report* as the standard to which they must comply.¹³⁶ The *Belmont Report* thus is the government’s benchmark for satisfactory licensing under the IRB laws, and it can serve this function because it expounds a general fiduciary duty for all human subjects researchers.

To justify the imposition of a fiduciary duty on such researchers, the federal government—as illustrated by the *Belmont Report*—glosses over the degree to which Nuremberg and Tuskegee involved government research and medical personnel.¹³⁷ The *Belmont Report* has to rely on Nuremberg and Tuskegee, for these are the preeminent moral anchors in arguments that researchers have a fiduciary duty, but the Report has to present these exemplars of misconduct in ways that avoid acknowledging that they more clearly illustrate the already familiar duties of government to those under its control and of medical personnel to patients.¹³⁸

¹³⁴ FEDERALWIDE ASSURANCE, *supra* note 42.

¹³⁵ *See id.*

¹³⁶ For one of innumerable examples, see Letter from Kristina C. Borrer, Compliance Oversight Coordinator, Div. Human Subject Prots., to Daniel R. Masys, Institutional Official for Human Subjects, Univ. of Cal., San Diego (Jan. 8, 2002), <http://www.hhs.gov/ohrp/detrmltrs/YR02/jan02c.pdf>. The letter responds to the publication of details of what appears to have been a Quality Improvement study, and although the letter acknowledges that there was “no evidence that a systematic prospective clinical trial was performed” and that thus the publication was not based on human subjects research, it quotes the *Belmont Report* to admonish the University. In fact, the letter was part of the government’s attempt to get universities to expand their understanding of human subjects research to include what might otherwise be considered “innovative therapeutic interventions.” *Id.* For further details of this letter, see *infra* note 180.

¹³⁷ The Nuremberg Code examined how medical experiments on human beings should “conform to the ethics of the medical profession.” THE NUREMBERG CODE: TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, at 181–82 (1949). For a discussion of Tuskegee, see *supra* notes 116–18 and accompanying text.

¹³⁸ Already in its fourth sentence—the *Belmont Report* states: “During the Nuremberg War Crimes Trials, the Nuremberg Code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners.” BELMONT REPORT, *supra* note 65, at 23,192. Later, in its discussion of the principle of justice, the Report alludes to Nuremberg and Tuskegee as part of the historical foundation for understanding “research involving human subjects”:

[T]he exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940s, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population.

Id. at 23,194.

This sleight of hand has not been without cost—one disadvantage being a misunderstanding about what was wrong about the Tuskegee Study. The *Belmont Report*'s version of Tuskegee raises questions as to whether the researchers there violated any duty to their subjects, and on the *Report*'s assumption that the Public Health Service officers at Tuskegee owed the duty of researchers, there has been some doubt as to whether they clearly violated any duty that was acknowledged at the time.¹³⁹ Of course, if it is recognized that the researchers were doctors and others who held themselves out as offering health care, then the breach of a Hippocratic and fiduciary duty is obvious. The *Belmont Report*, however, overgeneralizes about Tuskegee in terms of a general duty of researchers, and it thus leaves room for doubts as to what went wrong there.

The *Belmont Report*'s misleading overgeneralization from the examples of Nuremberg and Tuskegee has an even more serious consequence: It justifies the government's attempt to give researchers, as a profession, a fiduciary duty. For example, after initially relying on Nuremberg and Tuskegee as iconic illustrations of how researchers can endanger their human subjects, the *Belmont Report* argues that researchers should maximize benefits and minimize risks, and in support of this position it points to the Hippocratic principle that a doctor should "do no harm." The *Belmont Report* then self-consciously "extend[s]" this medical principle "to the realm of research," and although there had long been suggestions that *doctors* had a *moral* obligation to follow their Hippocratic duty when doing *medical* research—even perhaps when doing research on subjects who were not patients—the *Belmont Report* extends this medical duty to all researchers doing any human subjects research, whether medical, biological, or behavioral.¹⁴⁰ Thus, the misleading overgeneralization about Nuremberg and Tuskegee—that these were examples of how men failed to adhere to their duty as researchers—becomes the justification for treating researchers as if they have a fiduciary duty akin to that of doctors to their patients. From this perspective, IRBs do not interfere in inquiry or speech, but simply protect human subjects from breaches of the fiduciary duty that researchers, as a profession, owe their human subjects.

Yet researchers are not professionals. Doctors and lawyers voluntarily assume their fiduciary duties by undertaking to speak, think, or act for others. The IRB laws, however, impose a federal fiduciary duty on research-

¹³⁹ Hence, some of the revisionism about Tuskegee—although even according to the revisionist literature, there came a time when the researchers were clearly denying information and care that could have significantly helped at least some of the men. Thomas G. Benedek & Jonathon Erlen, *The Scientific Environment of the Tuskegee Study of Syphilis, 1920–1960*, in 43 PERSP. BIOLOGY & MEDICINE 1 (1999); Benedek, *supra* note 125; Richard A. Shweder, *Tuskegee Re-Examined: A Cultural Anthropologist Offers a Counter-Narrative to the Infamous Story of U.S. Government Scientists Allowing Black Men to Suffer from Untreated Syphilis*, SPIKED, Jan. 8, 2004, <http://www.spiked-online.com/Printable/0000000CA34A.htm>.

¹⁴⁰ BELMONT REPORT, *supra* note 65, at 23, 194.

ers, not because they volunteer to speak, think, or act on behalf of others, but because they seek to satisfy their curiosity—in particular, because they systematically seek generalizable knowledge through the study of human subjects.

The federal attribution of a fiduciary duty to researchers is evidently yet another penalty on the class *academicus* for inquiring with intent to learn—for doing what otherwise is lawful with a desire to develop scientific, publishable generalizations—and thus rather than justify the constitutionality of the licensing, the attribution of the fiduciary duty raises further constitutional questions. The government's requirement that each university or other institution commit to the "ethical principles" in the *Belmont Report* for "all . . . human subjects research, regardless of the source of support," leverages government grants to obtain a general ethical regulation of all human subjects research, and because the government thus imposes a fiduciary duty on individuals on account of their being at research institutions and their seeking "generalizable knowledge," this condition is of dubious constitutionality under the First Amendment.¹⁴¹ Even worse, the federal government's ambitious conditions have made the imposition of a fiduciary duty so widespread that state courts have begun to assume that it should be enforced by the law of negligence, and thus not only under federal law, but also under state law, interactions with fellow human beings that otherwise are examined under the general duty of care now are penalized with a severe fiduciary duty—not because the persons who initiate the interactions have voluntarily undertaken any professional duty, but rather because they are members of the inquisitive class and seek generalizable or publishable knowledge. Once again, it is doubtful whether this is constitutional.¹⁴²

More broadly, the government's use of licensing to impose the fiduciary duty on researchers reveals a further danger of licensing speech or the press. The federal government probably would have had difficulty in openly legislating a fiduciary duty for persons who never undertook to act for others, and it would have had even more difficulty enforcing such a duty in the courts, where the constitutional objections would have become manifest. The government, however, has had no difficulty enforcing this fiduciary duty through licensing, for licensing laws can leave the duties they enforce largely unelaborated. The fiduciary duty of human subjects researchers thus suggests a largely unexamined danger of laws that license speech or the press: Such laws offer government an opportunity to impose heightened duties that it could not otherwise adopt or enforce without running into political and constitutional obstacles.

¹⁴¹ FEDERALWIDE ASSURANCE, *supra* note 42.

¹⁴² See *Simon & Schuster v. Crime Victims Bd.*, 502 U.S. 105 (1991).

B. Imperfect Duties

The fiduciary duty that the government imposes on researchers includes “imperfect” duties, which are of a sort that is apt to conflict with the First Amendment. These imperfect duties thus confirm that the attribution of a fiduciary duty to researchers does not so much solve the constitutional problem as exacerbate it. More generally, the imperfect duties corroborate the observation that licensing of speech and the press too easily can become a means of enforcing duties that otherwise would be recognized as unconstitutional or otherwise inappropriate.

“Imperfect” duties are moral duties that are not enforced by law, but this is only the beginning of a definition.¹⁴³ It traditionally was thought that if legal or “perfect” duties had to be based on consent, and that if a people could not reasonably consent to duties that were not clearly and generally stated, then imperfect duties were those that could not be formulated with the clarity of rules—a conclusion that will be seen to give special significance to licensing as a means of enforcing imperfect duties.¹⁴⁴ More generally, imperfect duties could be considered those that cannot be legally enforced without intruding on the authority of individuals to make their own moral judgments. For example, although the duty of care is actionable at law as a perfect duty, the duties of charity, generosity, and kindness are not. In short, these imperfect duties cannot easily be reduced to enforceable rules of law and in any case cannot be imposed by law without undermining the freedom and moral authority of individuals, and because of this indeterminacy and intrusiveness, imperfect duties are particularly dangerous for the freedom of speech and the press.

Nonetheless, the federal government uses IRB licensing to burden researchers with a fiduciary duty that extends so far as to include imperfect duties. In asking universities to give assurances that they will adhere to the ethical principles of the *Belmont Report*, the government gets universities to commit to taking “[m]any kinds of possible harms . . . into account,” including “risks of psychological harm, physical harm, legal harm, social harm and economic harm,” and “[w]hile the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked.”¹⁴⁵ The National Science Foundation elaborates that IRBs should consider denying permission on account of the risks of “legal harm,” “financial harm,” “moral harm,” social “stigma,” or mental “upset” or “worry,” and as in the *Belmont Report*, this means not necessarily anything unlawful, but rather merely the possibility that inquiry or its publication will leave a human subject (or a group of which he is a

¹⁴³ SAMUEL PUFENDORF, *DE JURE NATURAE ET GENTIUM LIBRI OCTO* 315 (III.i.3) (James Brown Scott ed., Clarendon Books 1934) (1688).

¹⁴⁴ *Id.* at 119 (I.vii.8–9); *see also id.* at 441 (III.vii.9).

¹⁴⁵ BELMONT REPORT, *supra* note 65, at 23, 196.

part) in a worse position legally, financially, socially, or psychologically.¹⁴⁶ These are all real harms, but they are often the necessary and highly desirable consequences of freedom of speech and the press, and they are therefore imperfect to the extent they are caused by a researcher's lack of generosity or charity in exercising his rights under law. Some of these harms, moreover, are of a sort not ordinarily recognized as independent harms at common law precisely because a duty to avoid them would tend to be unclear and very intrusive on an individual's freedom and moral authority. For example, the government cautions IRBs that "[s]tress and feelings of guilt or embarrassment may arise simply from thinking or talking about one's own behavior or attitudes on sensitive topics such as drug use, sexual preferences, selfishness, and violence."¹⁴⁷ A duty to avoid causing these harms that might arise from inducing someone to think or talk is imperfect by any definition.

The *Belmont Report* concedes that the duties imposed by IRBs rise above the perfect duties ordinarily imposed by law. The common law tends to take cognizance of concrete, measurable injuries, and First Amendment doctrine often protects the freedom of speech and the press by taking a particularly narrow conception of injury. The *Belmont Report*, however, justifies its conclusions by reference to the higher principles of "Respect for Persons," "Beneficence," and "Justice"—the first being drawn primarily from Immanuel Kant, and the second having much in common with the theological assumptions of traditional Christian ethics.¹⁴⁸ It is not clear why

¹⁴⁶ Nat. Sci. Found., Div. of Institution and Award Support, Frequently Asked Questions and Vignettes, <http://www.nsf.gov/bfa/dias/policy/hsfaqs.htm> (last visited Sept. 19, 2004).

¹⁴⁷ IRB GUIDEBOOK, *supra* note 49, ch. III, pt. A.

¹⁴⁸ BELMONT REPORT, *supra* note 65, at 23,193–94. For the most traditional and elegant Catholic discussion of beneficence, see THOMAS AQUINAS, 3 SUMMA THEOLOGICA 1314 (pt. 2-2, Q.36) (Fathers of the English Dominican Province ed., Christian Classics 1981). The commission that drafted the *Belmont Report* acted with the advice of philosophers and at least one theologian and even published their extended musings with its report. The intellectual context of the time is suggested by Henry Beecher's famous article on research harms, which begins by observing that "according to Pope Pius XII . . . science is not the highest value to which all other orders of values . . . should be subordinated." Beecher, *supra* note 129, at 1354. Similarly, the government guidebook for IRBs specifies that universities should consider including "Ministers" on IRBs—as if clergy are especially apt licensors to act under governmental authority in judging what an academic may read, observe, ask, say, print, or publish. IRB GUIDEBOOK, *supra* note 49, at ch. I, pt. B. Even the government's educational films depict an IRB that features a clergyman. Videotape: Balancing Society's Mandates: Criteria For Protocol Review (Office for Protection from Research Risks, National Institute of Health 1986).

According to Robert Levine, "[b]ecause the Commission never articulated its concepts of ethical theory, the assumptions that follow are my own," but "they are based on my careful reading of all the Commission's publications as well as my participation in virtually all of the discussions that led to the writing of its reports." LEVINE, *supra* note 59, at 11. On this basis, he explains that "[t]he principle of respect for persons was stated formally by Immanuel Kant." *Id.* at 15. More generally, Levine notes that "[t]he Commission did not fail to choose among competing ethical theories." *Id.* at 11. Rather, being "[a]ware of Kantian (deontological), utilitarian, and Aristotelian traditions, for instance, the commission nonetheless refrained from relying on any one of them for the legitimacy of its conclusions. Agreement on a fundamental moral system was not sought or needed." *Id.* (citing Morris B. Abram &

the moral theory of a German idealist or of the Catholic Church is particularly helpful in understanding the practical ethics of American empiricism, but, more to the point, the *Belmont Report* self-consciously uses these elevated principles to make imperfect duties legally enforceable. As it explains about the principle of beneficence:

Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation.¹⁴⁹

In other words, beneficence is an imperfect duty, but it now would have the obligation of law as part of the federally-created fiduciary duty of researchers.

This imperfect duty of beneficence greatly exceeds the duty of doctors, for it moves beyond questions of injury to amorphous ideals of securing well-being. As noted above, the *Belmont Report* "extend[s]" the "Hippocratic maxim 'do no harm'" from "medical ethics . . . to the realm of research," and this attribution of a high fiduciary duty to persons who never undertook it is problematic enough. The *Belmont Report*, however, also recasts the Hippocratic principle as a principle of "beneficence," which turns out to mean something more ambitious than a doctor's Hippocratic duty—let alone his legal duty. Whereas the Hippocratic duty to a patient is that the doctor "should not injure," the duty of beneficence to human subjects turns out to mean that the researcher should "secure their well-being."¹⁵⁰

The heightened moral duties recited by the *Belmont Report* are irredeemably at odds with the pugilistic give and take of academic dispute. Whether stated in sweeping principles of justice, respect, and beneficence, or spelled out in admonitions to avoid ethereal sorts of harm, these are imperfect duties, and if imposed by law, they are fatal to robust intellectual and political debate. When a historian interviews a member of the Aryan Nations, or when a law professor interrogates a corrupt member of a zoning board, these scholars have a constitutional right to show no respect, to avoid beneficence, and to seek justice rather than merely do justice; they have a constitutional right to ask questions that could lead to mental, social, eco-

Susan M. Wolf, *Public Involvement in Medical Ethics: A Model for Government Action*, 310 NEW ENG. J. MED. 627, 630 (1984)).

¹⁴⁹ BELMONT REPORT, *supra* note 65, at 23, 194.

¹⁵⁰ *Id.* In justification, Levine suggests that "[t]he principle of *beneficence* is firmly embedded in the ethical tradition of medicine." As Levine acknowledges, however, "Hippocrates observed . . . make a habit of two things—to help, or at least to do no harm"—which means that although it should be a goal to help, the basic duty is to avoid harm. Nonetheless, the *Belmont Report* makes the moral ideal the basic duty, which under the IRB laws becomes a legal duty: "The principle of *beneficence* is interpreted by the Commission as creating an obligation to secure the well-being of individuals." LEVINE, *supra* note 59, at 17.

nostic, and legal harms; indeed, they ordinarily have even a constitutional right to seek such consequences. These imperfect harms are unavoidable elements of much empirical inquiry, and accordingly there is no room in such research for the legal imposition of philosophic, theological, or Hippocratic ideals about avoiding harm—let alone about doing justice, respecting others, or exercising beneficence.

Even in medical research, the ideals of justice, respect, and beneficence necessarily come into conflict with the dogged curiosity and pursuit of knowledge often needed for empirical discoveries. Thus, if government pursues social ends too vigorously—for example, with an expansive conception of imperfect harms rather than traditional conceptions of legally-cognizable harms—it will inevitably damage the unfettered, independent spirit that is essential for serious inquiry and the advancement of knowledge.

In the end, the legal imposition of a researcher's fiduciary duty, including even imperfect duties, does not justify the licensing; on the contrary, it just makes it worse. The fiduciary duty is of questionable constitutionality because it singles out researchers to be penalized on account of their pursuit of "generalizable knowledge"—on account of their pursuit of scientific and thus publishable generalizations.¹⁵¹ The imperfect duties comprised within the fiduciary duty aggravate the problem because they are a sort of duty that tends to be incompatible with the freedom of speech and the press.

More generally, the imposition of these fiduciary and imperfect duties illustrates one of the dangers of licensing. It is notorious that the licensing of speech and the press can be used to enforce ill-defined substantive duties. Licensing thus offers a mechanism for enforcing duties of a sort that if stated and enforced more openly in after-the-fact penalties would run up against political and constitutional impediments, and this is yet another reason—as if any were necessary—to consider licensing a singularly dangerous method of regulating speech or the press.

IV. HARMS

The IRB laws are usually justified as a means of preventing harms. Human subjects can suffer serious injury, and claims about research harms have therefore seemed to substantiate arguments that the government has an interest in preventing research harms. From this perspective, the government's interest in preventing the harms can overcome the heavy constitutional presumption against the constitutionality of prior restraints.

It is doubtful, however, whether the government interest in preventing research harms overrides so heavy a constitutional presumption—a presumption "heavier . . . than that against limits on expression imposed by

¹⁵¹ See *Simon & Schuster v. Crime Victims Bd.*, 502 U.S. 105 (1991).

criminal penalties.”¹⁵² The First Amendment, as seen in Part I, flatly barred any law licensing speech or the press, without regard to government interests, and although the Supreme Court has said that a sufficiently strong government interest can justify a prior restraint, it is improbable that the government’s interest in preventing harms can justify the licensing of verbal language, spoken or printed—especially as there are other means of addressing the harms that do not abridge the freedom of speech or the press.¹⁵³

In fact, rather than support any argument about an overriding government interest, an examination of the harms suggests that the argument about government interest is contaminated with popular prejudice. There never has been serious empirical evidence that human subjects research is particularly harmful or that IRBs are efficacious in preventing harm—indeed, it is manifest that IRBs cause more harm than they prevent—and this raises a sobering question as to whether the federal government adopted its sweeping system of licensing not so much in response to actual harms as in response to popular fears and anxieties.

A. The Body Count

The justification for the IRB laws typically comes in the form of a body count, but the numbers do not quite add up. The grim stories about human subjects who have died after research went awry are apt to leave one with a visceral feeling that regulation is needed. The body count of research subjects, however, only examines the losses on one side, and therefore the accounting needs to be more complete. On the one hand, the harms from the research must be considered more systematically; on the other hand, the harms from licensing need to be taken into account. In the end, it is difficult to find much empirical evidence that the research is particularly dangerous, and the greater danger appears to come from the IRBs themselves, which suppress essential, often lifesaving research.

¹⁵² *Southeastern Promotions, Ltd. v. Conrad*, 420 U.S. 538, 558–59 (1975).

¹⁵³ Of course, the harms that a law attempts to prevent are not by themselves the measure of the government interest that judges consider when evaluating the line between the right of an individual and the power of government, for the government interest that informs such a decision is a general consideration of the sort of interest government may lawfully pursue—not the need to pursue it in particular legislation, which, in contrast, is a matter of legislative policy.

The Court’s doctrine on government interests is of particularly little help in justifying laws licensing speech or the press—in the sense of verbal language, spoken or printed—because it is improbable that any system of licensing speech or the press could ever be narrowly tailored to match even the strongest government interest in preventing harm. As observed earlier, licensors must judge the potential for harm before it has occurred, and therefore licensors usually can prevent harm only by barring much innocent activity. This is particularly a problem in the licensing of speech or the press, for the harms of speech or the press are apt to be somewhat speculative. Accordingly, any law requiring licensing of speech or the press is likely to leave much harmless use of speech and the press at risk of being denied permission. Thus, although a government interest in preventing harm could justify after the fact penalties on actual harms, no such interest could be narrowly tailored to justify a law licensing speech and the press.

Deaths from research are not the only measure of harm, but deaths are a particularly serious harm, and they are the measure most commonly adopted by advocates of IRBs. The actual rate of death is bound to be higher than what can be measured, for even when research causes the death of a human subject, the causation may not be discernable. Nonetheless, the deaths known to have been caused by human subjects research are a valuable measure of the scale of the danger, and this is especially true because such deaths have been the subject of painstaking scrutiny for at least three decades. Although the scrutiny applied to such deaths has increased dramatically since about 1970, there have been extensive retrospective studies reaching back to World War II.¹⁵⁴ Accordingly, even if the rate of death is a very imperfect measure of the harm to human subjects, it is as good a measure of the scale of danger as is available.

Of course, to understand the harms from the IRB laws, this calculation of known deaths must exclude the deaths arising from any testing of drugs and devices under FDA regulations. The IRB laws under consideration here are those that impose licensing on human subjects research in general. In contrast, the FDA regulations that use IRBs to permit tests of otherwise prohibited drugs and devices do not clearly impose licensing on speech or the press and therefore are not in question here. Thus, although the harms from this drug and device testing may be relevant for an evaluation of the IRB licensing under the FDA regulations, such harms cannot justify the IRB laws that generally concern research. As it happens, even the FDA-covered research, when considered overall, is not as risky as might be supposed, but rather than confuse two different regulatory schemes, the calculation of deaths here excludes the sort of drug and device testing that today is covered by FDA regulations.

There apparently is no statistical survey of the deaths known to have been caused by human subjects research, but in an examination of the extensive literature, it is difficult to find instances in which such research is known to have caused the death of a human subject more than a handful of times during each decade over the course of the last half century.¹⁵⁵ It ap-

¹⁵⁴ See, e.g., *Cold War Era Human Subject Experimentation: Hearing Before the H. Legislation and Nat'l Sec. Subcomm. of the Comm. on Gov. Operations.*, 103d Cong. (1994); Beecher, *supra* note 129.

¹⁵⁵ Although Beecher notes one instance in which the evidence that the research subject died from the research "was considered conclusive," his other conclusions about deaths are based on very general statistical comparisons, and without much more information about the particular studies and the individuals included in them, it is difficult to draw strong conclusions. Beecher, *supra* note 129, at 1359.

Beecher's most specific and dramatic case of multiple deaths, his case number 3, illustrates how little can be discerned from his cursory descriptions of complex situations. Beecher complains that the researchers withheld what was known to be an effective treatment, but according to Beecher himself the researchers did not yet know the long term effectiveness of the drug in question and in fact were attempting to determine the relapse rate. *Id.* at 1356. His omission of identifying details, moreover, leaves the impression that the case offers evidence about American research, but in fact it occurred in

pears, moreover, that the rate of death has remained relatively stable. For example, there is no evidence of significantly higher death rates in the 1950s and 1960s, when much research was conducted without IRBs, compared to the 1970s, 1980s, and 1990s, when research was increasingly subjected to IRB review. This calculation of known deaths inevitably is rough and contingent, and it obviously is not a measure of actual deaths, but in light of all the work that has been done to document the deaths of human subjects, it is remarkable how few deaths per decade can be shown to have been caused by human subjects research.¹⁵⁶

On the reasonable assumption that the data nonetheless undercounts deaths, one could multiply the outer range of known deaths by a factor of ten, but there still would be no more than five deaths per year. Even if one were so skeptical of the data as to multiply the known deaths by 100, one could assume no more than fifty deaths per year. This number would be tragic, but it is a tiny fraction of the deaths caused by many other mundane activities, licensed and unlicensed, and it would not seem even remotely sufficient to justify what otherwise would be a violation of the First Amendment—let alone a sweeping licensing system reminiscent of the era of Milton.¹⁵⁷

The federal government, in fact, has long acknowledged the harmlessness of entire categories of the research licensed under the IRB laws. In 1966, when the government was beginning to develop its IRB requirements,

the Philippines. Pedro T. Lantin, Sr., Alberto Geronimo, & Victorino Calilong, *The Problem of Typhoid Relapse*, 78 AM. J. MED. SCI. 293 (1963).

At Tuskegee “[t]he available treatment might have exerted a definitely beneficial effect on the prognosis of only 12.5% of the subjects.” See Benedek, *supra* note 125, at 232. It is not clear, however, to what degree the failure of the researchers to inform the men about penicillin actually caused any deaths among the men, particularly as many of them independently sought out penicillin.

¹⁵⁶ Edward Pattullo writes:

Despite the handful of horror stories, the record of the professions in protecting their human subjects is remarkably good, in all fields, I believe, though I now address just the behavioral and social sciences. If one includes survey research, millions upon millions of subjects have been “used” in this century. Despite intense inquiry (some conducted by individuals whose concern for subjects seems a surrogate for worries about unrelated problems of modern society), it appears the actual harm done by this vast enterprise is negligible. Thus, any margin of additional protection that the IRBs provide represents an inconsequential gain.

Edward L. Pattullo, *Institutional Review Boards and Social Research*, in NIH READINGS ON THE PROTECTION OF HUMAN SUBJECTS IN BEHAVIORAL AND SOCIAL SCIENCE RESEARCH: CONFERENCE PROCEEDINGS AND BACKGROUND PAPERS 10, 13–14 (Joan E. Sieber ed., 1984).

¹⁵⁷ One can consider a range of other activities, both licensed and unlicensed. The former include driving, which leads to more than 40,000 deaths each year, and visiting a doctor, which by one estimation leads to “over 150,000 iatrogenic fatalities annually, more than half of which are due to negligence.” TOM BAKER, *THE MEDICAL MALPRACTICE MYTH* 30 (2005); see also *id.* at 5. More moderately, bicycling leads to about 700–800 deaths *per year*, and walking leads to about 4000–5000 deaths *per year*—merely from traffic crashes. National Highway Traffic Safety Administration, Traffic Safety Facts, 2005 Data, for Bicyclists, <http://www-nrd.nhtsa.dot.gov/pdf/nrd-30/NCSA/TSF2005/BicyclistsTSF05.pdf> (last viewed on Dec. 10, 2006); for Pedestrians, <http://www-nrd.nhtsa.dot.gov/pdf/nrd-30/NCSA/TSF2005/PedestriansTSF05.pdf> (last viewed on Dec. 10, 2006).

IRBs still were relatively novel and therefore could not have been the explanation for an absence of harm. Yet when the Surgeon General that year announced that the government would require IRBs not only for federally funded biomedical research but for “all investigations that involve human subjects, including investigations in the behavioral and social sciences,” he conceded that “there is a large range of social and behavioral research in which no personal risk to the subject is involved.”¹⁵⁸

It is not even clear that medical research—including the drug and device testing covered by FDA regulations—is particularly dangerous. E.L. Pattullo reports in the *New England Journal of Medicine* that:

Of 2384 research projects surveyed in 1974–1975, 3% were reported to have caused harmful effects to a total of 158 subjects, with most of the harm characterized as “trivial or only temporarily disabling.” Given the size of the research enterprise (\$8 billion of health-related research in 1980) and the number of subjects involved annually, the incidence of injury appears extremely small.

From this, he concludes that the regulation of harm to human subjects “cannot be accounted for by the record of injury to subjects.”¹⁵⁹ Robert Levine reaches similar conclusions. In 1978, he was a Special Consultant to the National Commission that outlined what eventually became the Common Rule, and he subsequently wrote a leading text on IRBs.¹⁶⁰ He observes that “[m]uch of the literature on the ethics of research . . . reflects the widely held and, until recently, unexamined assumption that playing the role of research subject is a highly perilous business,” and as he has good reason to know, this assumption was “clearly evident in the legislative history” of the 1970s. He finds, however, that “some empirical data have become available” that “indicate that, in general, it is not particularly hazardous to be a research subject.”¹⁶¹ Writing on the basis of risk studies done up through 1981, when the IRB regime was significantly less intrusive than it became over the following decades, Levine found that the overall risk of being a research subject was not very high. The evidence further suggested that in “‘therapeutic research’ . . . the risk of either disability (temporary or permanent) or of fatality was substantially less than the risk of similar unfortunate outcomes in other medical settings involving no research.” He concludes that “the role of research subject is not particularly hazardous in general” and that “arguments for policies designed to restrict research generally be-

¹⁵⁸ Bradford H. Gray, *The Regulatory Context of Social and Behavioral Research*, in *ETHICAL ISSUES IN SOCIAL SCIENCE RESEARCH* 329, 331 (Tom L. Beauchamp, Ruth R. Faden, R. Jay Wallace, Jr. & LeRoy Walters eds., 1982).

¹⁵⁹ E.L. Pattullo, *Institutional Review Boards and the Freedom to Take Risks*, 307 *NEW ENG. J. MED.* 1156, 1156 (1982). Most but not all of the surveyed research projects involved medical research, and many evidently involved drugs.

¹⁶⁰ ROBERT J. LEVINE, *ETHICS AND REGULATION OF CLINICAL RESEARCH* (1981).

¹⁶¹ *Id.* at 25.

cause it is hazardous are without warrant.”¹⁶² Undoubtedly, particular research projects can be relatively hazardous, and Levine had to work from studies done after the introduction of IRBs, but the overall risk from research on human subjects appears to be quite mundane.

Nor is there empirical evidence that IRBs significantly reduce the overall harms from research. It is clear that IRBs sometimes reduce the harm from particular research projects, but this by itself does not reveal much about the general efficacy of IRBs in preventing research harms. One problem is that the very existence of IRBs may lead some researchers to feel less responsible for protecting their subjects.¹⁶³ More generally, the absence of much change in the known death rate would seem to suggest that IRBs have not had a discernable effect. In the end, however, the efficacy of IRBs in preventing research harms remains largely a matter of speculation. The awkwardness is that the government adopted IRBs without a controlled study of their efficacy in reducing harms, and the subsequent attempts to

¹⁶² *Id.* at 25–26. He adds: “Equally unsupportable are arguments that, because research is generally safe, there is no need for any restriction.” *Id.* at 26. In a 1982 survey of the risk of injury, Levine and Mary Harvey conclude that their “study suggests a low incidence of research-related injuries.” Mary Harvey & Robert J. Levine, *Risk of Injury Associated with Twenty Invasive Procedures Used in Human Experimentation and Assessment of Reliability of Risk Estimates*, in 2 COMPENSATING FOR INJURIES: A REPORT ON THE ETHICAL AND LEGAL IMPLICATIONS OF PROGRAMS TO REDRESS INJURIES CAUSED BY BIOMEDICAL AND BEHAVIORAL RESEARCH 79 (1982). Although they note deaths, their evidence only concerns the overall risk of injury, not the cause of any particular deaths, and their evidence includes reports of drug trials.

A study done for the National Commission that drafted the *Belmont Report* found that: “Overall, harm to subjects was reported in three percent of the projects. These harms were generally considered trivial or only temporarily disabling. Three investigators [out of more than 2000 interviewed] reported fatal effects; in each of two projects one subject died and in one project three subjects died. Each of these projects involved cancer research, and in two of the projects some subjects were near terminal conditions at the time of their participation in the research.” NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, DHEW PUBLICATION N. (OS) 78-0008, REPORT AND RECOMMENDATIONS INSTITUTIONAL REVIEW BOARDS 63 (1978). Such research probably included drug trials.

Dr. Robert Cooke—Vice Chancellor for Health Sciences at the University of Wisconsin and one of the members of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research—attempted to remind the Commission about the real risks of therapeutic and nontherapeutic research:

[T]he thing that we used to call nontherapeutic is not only relatively non-risky, it seems to be safer to be a subject in nontherapeutic research, than to walk out in the world.

You have less chance of being injured as a subject of what they call nontherapeutic research, than the ordinary citizen has of being injured in an accident.

And if you want to find risks, the place you find it, is in what they call therapeutic research. Eight percent of those people died. But if you compare the risk of being a subject in therapeutic research, with the risk of being a patient with the same sort of disease in the same sort of hospital, you are a heck of a lot safer being a subject in therapeutic research.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Transcript of the Meeting Proceedings (26th Meeting), at 2–72 (meeting of Jan. 8, 1977) (U.S. Department of Commerce, National Technical Information Service, January 1977).

¹⁶³ See *infra* text accompanying note 191.

examine the question have run into a host of obstacles, such as the secrecy of IRB proceedings and the difficulty of setting up a control group to measure the effects of IRBs after these boards came to be required by law.¹⁶⁴

The injured human subjects, however, are only one side of the equation, for their numbers must be weighed against the sum of all the persons who died or otherwise suffered because IRBs left them without the benefits of research. The value of institutions obviously cannot be measured simply by adding up lives on either side of a metaphorical ledger, but after so many decades of an entirely one-sided body count, a more balanced form of accounting can at least put the deaths from research in perspective. By licensing inquiry done with intent to learn “generalizable knowledge,” by altering or altogether suppressing inquiries, by denying researchers permission to ask, say, write down, or publish what seems too “sensitive,” and by requiring the destruction of data, IRBs repeatedly interfere with advances in knowledge.¹⁶⁵ Over 100,000 research proposals are modified by IRBs every year, and much other research is self-censored, abandoned, or not even started for fear it will not get approved. Even if most of the modified and abandoned research would not have created substantial benefits, one only has to assume that one in 100,000 projects would otherwise have had profound benefits to understand the loss caused by IRBs. A single educational, epidemiological, or medical study can transform the lives of countless individuals—whether by giving rise to a lifesaving invention or treatment or by prompting a new government policy—and if only one such project in 100,000 gets stymied by an IRB, the loss to humanity over the decades almost certainly exceeds the loss from the research by a very substantial factor. Of course, the losses from IRBs are impossible to measure accurately, but they are probably enormous, and it is therefore tragic that a largely “unexamined assumption” was used to justify an unconstitutional and deeply harmful system of licensing.¹⁶⁶

Were IRBs to license only medical research, they would still be worrisome, for medical progress has often been a story of rebellion against the narrow morality of majorities. Frequently, what persuades doctors and academics is not a research proposal, but the demonstration of a successful re-

¹⁶⁴ Although it is plausible that research at private companies could be used as a control, even this may be difficult to the extent the use of IRBs has become the standard of care for human subjects research.

A recent study purports to show that IRBs have reduced deaths in Phase 1 clinical trials of cancer drugs. Thomas G. Roberts et al., *Trends in the Risks and Benefits to Patients with Cancer Participating in Phase 1 Clinical Trials*, 292 J. AM. MED. ASS’N 2130 (2004). As acknowledged by the author, however, the data is primarily explained by the decreased toxicity of cancer drugs during the period examined and by the introduction of better supportive care. In this context, the suggestion that IRBs played a role in reducing the deaths is purely speculative. Incidentally, such a study—done without a control group—would not ordinarily meet the standards of scientific method that IRBs themselves impose.

¹⁶⁵ For “sensitive,” see IRB GUIDEBOOK, *supra* note 49, at ch. III, pt. A.

¹⁶⁶ LEVINE, *supra* note 59, at 25.

sult in the experimental study or treatment of a human being, and it is therefore difficult to believe that the introduction of IRBs and their enforcement of “community attitudes” has not seriously delayed the development of medical advances.¹⁶⁷ As observed by the chair of the Biological Sciences IRB at the University of Chicago, “[w]hile we can agree that the development of X-rays, heart catheterization, and anesthesia are sentinel [sic] events in medicine, I reluctantly conclude that the web of institutional and federal regulations would make it very unlikely that these advances could be developed in 2005.”¹⁶⁸ Of course, medical researchers can be held liable for negligently inflicting injury, and when dealing with their own patients, they owe a high fiduciary duty. The advancement of knowledge, however, needlessly suffers if they are not merely penalized after the fact for causing legally-cognizable injuries, but are also prejudged by licensing boards that examine their research for its conformity to a stifling communal morality.¹⁶⁹

Outside medicine, there has been a dramatic decline in entire fields of empirical research because of IRBs. Educational researchers no can longer easily observe students in their schools; doctors and social scientists who want to study what prudish IRBs consider “sensitive” matters, such as marriage or sexuality, must often try to do their research without talking to the persons they are studying; Ph.D. students in empirical fields now frequently graduate without having ever done their own empirical research, because

¹⁶⁷ For “community attitudes,” see 45 C.F.R. § 46.107(a) (2005).

¹⁶⁸ Jonathan Moss, *The 482nd Convocation Address: Could Morton Do It Today*, U. CHI. REC., Jan. 5, 2006, at 27. Although a supporter of IRBs, he has

a growing concern about the barriers these regulations impose on new ideas—barriers that can be so daunting as to discourage innovation. As Institutional Review Board chair, I have seen many of our own young investigators drift away from clinical research because of these challenges. My experience is with medical research, but I suspect that the problem of maintaining innovation in an increasingly regulated environment may well be a more general one.

Id. at 27–28. Although largely speaking of FDA regulated drugs and devices, his point is illustrative of the broader problem.

¹⁶⁹ Perhaps the most poignant medical illustration is the effect on Quality Improvement studies. In these studies, doctors evaluate treatments in the hope of improving outcomes, and they thereby often save lives. Not surprisingly, such studies are often done by academic doctors, who thus bring their skills to bear on medical practice, and who hope to publish any generally applicable knowledge that they may learn. Now, however, because of the potential for publication, such studies are increasingly treated as research that requires prior IRB approval, and if a doctor publishes such a study without having earlier gotten permission, he must worry that the IRB will investigate him and injure his career. Accordingly, when doctors do Quality Improvement studies without prior permission and come across valuable “generalizable knowledge,” they now have incentives to leave this information unpublished. The danger is all the greater because, even more than most types of research, Quality Improvement studies are difficult to get through IRBs—the reason being that they require continual tinkering and thus are not easily reduced to the formal research proposals required by IRBs. Academic doctors therefore have reason not only to avoid publishing the results but also to avoid doing the studies in the first place, for they traditionally had done such work on account of the potential to publish, but now if they hope to publish, they first must undergo the burden of getting approval for the study—even though they will not know until afterward whether it will lead to a publication. This issue has been pointed out to me by various doctors and researchers whom I cannot cite.

they cannot satisfy IRB requirements within the time necessary to complete their coursework; geneticists sometimes forgo learning about the diseases recorded in tissue banks, lest they spend most of their research time satisfying the requirements of an IRB.¹⁷⁰ The situation is well summed up by Margaret Blanchard—a distinguished professor of journalism—who wrote in 2002 that she was “leaving the contemporary period behind. It is far safer in the nineteenth century. . . . [Y]ou do not have to worry about the IRB when you work in the nineteenth century.”¹⁷¹ One professor in her department says “he now limits his class projects to ‘bland topics and archived records.’”¹⁷² Blanchard notes, “I have seen students alter research projects to avoid IRB contact. I have seen some give up projects because of the red tape involved. I have heard words such as ‘thought control’ used far too often.”¹⁷³ She concludes: “A better formula for stultifying research is beyond contemplation.”¹⁷⁴

In the course of stifling empirical inquiry, the government does particular harm by barring empirical critiques of government policies and programs. Although current theories of the First Amendment focus on mere opinion, political debates can be all the more effective when based on the scientific knowledge acquired through empirical inquiry. Over the past several centuries, the study of politics has tended toward empiricism—toward the study of the world as it is, rather than as it should be—and in an era of expanded federal power, the empirical study of federal programs is of particular importance. Only with the knowledge acquired through empirical inquiry can individuals efficaciously criticize or advocate such programs. Yet in the 1960s and 1970s, when the federal government dramatically expanded its reach into the lives of Americans, it also established the IRB licensing system, and it thus squelched a wide range of inquiry into the actual

¹⁷⁰ Even merely the loss in time for scholars who must comply with IRBs diminishes research, for many scholars and students find the delay, obstacles, and interference so annoying that they simply abandon the study of human subjects and pursue other inquiries.

The delays and burden of paperwork prevents students from doing their own empirical work in their courses, and the consequences for the transmission of empirical skills to a new generation of scholars can be illustrated by the decision by the Journalism Department at the University of Missouri at Columbia that it “will no longer require scientific research for masters candidates.” *University of Missouri Amends Research Paper Policy*, STUDENT PRESS L. CENTER REP., Spring 2002, at 17, available at http://www.splc.org/report_detail.asp?id=818&edition=21. In a less formal way, this is a tendency at almost all universities. This conclusion comes from personal conversations I have had with teachers and students from various institutions.

¹⁷¹ *Should All Disciplines Be Subject to the Common Rule?*, ACADEME, May–June 2002, at 62, 68. (comments of Margaret Blanchard).

¹⁷² *Id.*

¹⁷³ *Id.*

¹⁷⁴ *Id.* Of course, outside journalism departments, journalists every day ask questions that cause very serious legal, economic, reputational, and emotional harm—as can be illustrated by the suicides triggered by journalistic inquiry. For a recent example arising from a television interview, see Travis Reed, *Mother of Missing Boy Commits Suicide*, ASSOC. PRESS, Sept. 13, 2006.

effects of federal programs. For example, whereas anthropologists, sociologists, psychiatrists, and political scientists once did detailed field studies on poverty, sex, education, and health and thereby led the way in demanding, critiquing, and shaping government programs on these matters, academics can no longer do such studies without first getting an IRB's permission. They thus can challenge the government only by getting their research pre-approved by the government's licensors, and they thus learn to tame their questions, to use methods that conform to the taste of the IRBs, and to avoid the sort of identifying detail that made earlier empirical studies so persuasive. After three decades of thus submitting to the authority of government, many human subjects researchers appear to have accepted that they lack any independent authority to study government programs, and certainly academic field work now has much less of the radicalism or significance it once had.

The propensity of IRBs to do more harm than they prevent is not surprising, for licensing systems tend to be disproportionately severe when used to eliminate harms. Rather than establish a rule against an injury and leave individuals to avoid it, licensing prohibits an entire category of conduct and then gives administrative boards authority to permit the conduct, depending on their assessment of the potential for harm. Licensing boards thus must judge the risk of harm before it occurs, and they therefore can be confident of preventing all harm only at the cost of barring much activity that will turn out to be utterly harmless. Of course, many licensing schemes, such as those concerning marriage or driving, do not disproportionately stand in the way of harmless activity, for rather than attempt to prevent the full range of harms, they merely aim to bar some particularly obvious risks, such as drivers who are underage or who cannot complete a simple driving test.¹⁷⁵ Yet when licensing schemes attempt to prevent all relevant harms, they are apt to bar much harmless activity. This is not too high a price to pay where the probability or degree of harm is peculiarly great—such as in the licensing of nuclear power plants. Yet when government licenses ordinary acts, for which both the probability and the degree of harm are mundane, with the goal of thoroughly preventing the harms, there is much reason to fear the usual dynamic—that in their efforts to prevent ordinary harm, licensors will disproportionately prevent conduct that is harmless and highly beneficial.

In short, IRBs are far more dangerous than the research they review. Although a single IRB can usefully prevent harm in a particular research project, the policy of imposing IRBs must be considered as a whole, with respect to human subjects research in general, and this reveals that IRBs cause much more harm than they prevent. When both sides of the ledger

¹⁷⁵ Another exception is when the licensed conduct itself is directly injurious, for in such instances licensors can anticipate with certainty when harm will ensue. In most licensing schemes, however, the ensuing injury is only a matter of probability.

are counted, the harm to human subjects pales in comparison to the harm to all those who might have benefited from the lost research, and this raises a question as to how the government came to consider human subjects researchers so dangerous.

B. Human Subjects and Inhuman Researchers

In the absence of much empirical evidence of harm, it must be wondered how the government came to believe human subjects research needed to be licensed, and the answer can be observed in the government's distinction between researchers and their human subjects. At the time the government adopted the IRB laws, the distinction between researchers and human subjects seemed to support the need for IRBs, but in retrospect, the distinction reveals the degree to which the government adopted its perception of harms in response to unsupported presuppositions—indeed, in response to popular fears and prejudices.

The literature on IRBs repeatedly emphasizes that researchers have the potential to follow in the footsteps of the doctors at Auschwitz, and that those whom they study become mere subjects—the passive objects of their unrestrained curiosity.¹⁷⁶ It is as if a researcher could become Dr. Frankenstein, and his subjects, his helpless victims. In this nightmare vision, researchers are transformed by their curiosity into potential monsters, and their subjects, upon contact with researchers, are rendered too supine to protect themselves.¹⁷⁷

The labels contribute to the sense of anxiety. The word “researcher” lumps together a Mengele and a Milgram, thus suggesting that each is equally a researcher who endangers the dignity of his subjects and so needs government regulation.¹⁷⁸ Similarly, the phrase “human subjects” includes both a concentration camp victim and a town official in Poughkeepsie who

¹⁷⁶ Almost all accounts of how IRBs are needed to prevent the dangers of human subjects research begin with the experiments in Nazi concentration camps, and this is true not only of popular studies but also supposedly sober academic accounts. Nuremberg, for example, is the opening example in the *Belmont Report*. See *supra* note 138.

¹⁷⁷ Patients often become passive in hospital settings or in the hands of their doctors, and perhaps subjects who are not patients adopt a similar attitude when studied in a hospital or by a doctor, for they may be under the impression that in these situations they are owed a fiduciary duty. Such passivity, however, does not appear to extend outside these circumstances, as can be illustrated by the low response rates to surveys.

¹⁷⁸ This lumping together of Milgram with Mengele and his colleagues becomes explicit in the government education films, such as *Evolving Concern: Protections for Human Subjects*, which, as Richard O'Brien observes, “opens with a collage of four pictures showing (1) Nazi researchers at Nuremberg, (2) the Tuskegee Study, (3) the Wichita Jury Study, and (4) Stanley Milgram's (1974) obedience research.” O'Brien, *supra* note 112, at 33. O'Brien comments: “While there is some disagreement on the ethics of Milgram's experiment, would anyone group his work with that of the physicians at Tuskegee or the Nazis tried at Nuremberg?” *Id.*

is interviewed by a local student.¹⁷⁹ Yet when a mere colloquy gets characterized as “human subjects research,” or when a mere reading project or written survey becomes an “experiment,” does the researcher really become a nascent predator, and his “human subjects,” potential victims?

This tendency to generalize about researchers and human subjects is profoundly dangerous, for it lends credence to laws that treat researchers and subjects as incapable of exercising individual authority. Researchers come to seem incapable of responsibility toward others, and their subjects come to seem incapable of responsibility for themselves—thus making it necessary for IRBs to license the researchers in their curiosity and the subjects in their consent. For example, the commission that established the foundations for what became the Common Rule argued that “investigators” must be deprived of their individual authority on account of their curiosity:

[I]nvestigators should not have sole responsibility for determining whether research involving human subjects fulfills ethical standards. Others, who are independent of the research, must share this responsibility, because investigators are always in positions of potential conflicts by virtue of their concern with the pursuit of knowledge as well as the welfare of the human subjects of their research.¹⁸⁰

From this perspective, the entire class of “investigators” is without sufficient capacity to make responsible individual judgments about their con-

¹⁷⁹ Although the Common Rule offers an exemption that might initially seem to cover the interview with the politician, it is not much of an exemption. The Common Rule exempts

[r]esearch involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

45 C.F.R. § 46.101(b)(3) (2005). As it happens, “public officials” is understood to mean only those who are public figures, and the phrase thus does not cover most local politicians. Hamburger, *supra* note 6, at 299–300. Some IRBs, moreover, have not even exempted the study of major figures, such as Ronald Reagan and federal judges. The meaning of the phrase, however, is beside the point because the government expects even exempt research to get prior IRB permission. See *supra* notes 53–54.

¹⁸⁰ NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, *supra* note 162, at 1.

The government is so eager to prevent individuals from reaching their own decisions about their conformity to law that it not only requires IRB licensing but also uses its site visits to encourage universities to establish additional committees to pre-review proposals “to determine in advance whether a particular intervention involves human subject research and should be conducted under an IRB-approved protocol.” Letter from Kristina C. Borrer, Compliance Oversight Coordinator, Div. of Human Subjects Protections, Dep’t of Health and Human Servs., to Daniel R. Masys, Institutional Official for Human Subjects, Univ. of Cal., San Diego (Jan. 8, 2002). In pursuit of this policy, OHRP even asked some universities, such as the University of Chicago, to provide an assurance that their researchers will get permission to treat their research as exempt. Univ. of Chicago, Multiple Project Assurance of Compliance with DHHS Regulations for Protection of Human Research Subjects, at pt. III.B (on file with author). For details, see *supra* note 108. The government is clearly seeking an additional layer of licensing to decide what requires licensing.

formity to law or morals, because they have a “concern with the pursuit of knowledge”—because they have curiosity. The Commission did not explain why curiosity corrupts individual judgment more than other forms of self-interest. Certainly, what is far more dangerous than curiosity is for government to single out persons on account of their curiosity—on account of their attempts to learn “generalizable knowledge”—and to require them to get permission before they begin their inquiries, before they talk to anyone, and before they share or otherwise publish what they learn.

Although the government in the 1970s found a political opening for the adoption of IRB laws in the public reaction to the Tuskegee study, the government adopted its sweeping licensing of human subjects researchers in response to deeper public anxieties about scientific inquiry and modernity. As observed by one contemporary, some of the “intense inquiry” about harm to human subjects was “conducted by individuals whose concern for subjects seems a surrogate for worries about unrelated problems of modern society.”¹⁸¹ In an era in which scientists, not unlike Dr. Frankenstein, seemed to have so much power over life and death as to be able to remake humanity, Americans came to fear human subjects researchers.¹⁸² Recognizing the role of these fears, some commentators explain that the government needed to adopt the IRB laws to overcome the popular fears of research that left many individuals reluctant to participate as human subjects. Yet to assuage popular fears about those who seek scientific generalizations by imposing licensing hardly overcomes the First Amendment objections.

In light of the popular anxieties about human subjects researchers, it is no surprise that the government has ended up cordoning off these researchers from the rest of society. Treating them as peculiarly dangerous on account of their desire for generalizable knowledge, the government separates them from those with whom they would engage, even if only to talk, and thus isolates the researchers—not physically, with barbed wire, but legally, with rules that deny the researchers, on account of their curiosity, the freedom to engage in otherwise lawful interactions with their fellow human beings. Any other individual can decide for himself how to interact with other persons, whether when talking with them or sticking foreign objects into them, and the risk of a legal remedy is usually more than enough to persuade Americans to interact with one another with appropriate care. For example, if a diabetic is too squeamish to inject himself with insulin, a

¹⁸¹ Pattullo, *supra* note 156, at 11. Pattullo observes that “memories of Nazi atrocities were fresh,” but “[e]ven more important . . . America’s long love affair with science (like all grand passions) was beginning to cool.” *Id.*

¹⁸² For a brief survey of post-War newspaper responses to human subjects research, see Memorandum from Rebecca Lowen to Members of the Advisory Committee on Human Radiation Experiments Re: Representation of Experiments Using Human Subjects in Newspapers and Periodicals, 1946–1981 (Apr. 4, 1995), http://www.gwu.edu/~nsarchiv/radiation/dir/mstreet/commeet/meet13/brief13/tab_d/br13d2.txt.

neighbor can volunteer to do it, and ordinarily will do it well, without needing permission from a neighborhood review board. Some Americans, however, cannot interact with their fellow human beings without first asking an IRB, for they interact with intent to learn—indeed, with intent to learn scientific generalizations—and they thus cannot be trusted to decide for themselves whether and how they should have contact with others.

This isolation of researchers can seem very satisfying if one shares popular anxieties about them, for it places this dangerous class and their dangerous enterprise in a box from which they cannot escape without prior permission. In the end, however, Pandora can no more be confined in a box than what she desires to know, and even if worldly knowledge is a mixed blessing, the greatest danger lies in crude attempts to restrict such knowledge and those who seek it. Of course, the use of licensing of speech and the press to confine the curious in their pursuit of generalizable knowledge surely prevents some real harm. Yet particularly in the absence of empirical evidence of wide-scale harm, the licensing more clearly circumscribes research within popular fears.

V. SCIENTIFIC KNOWLEDGE

Although the First Amendment bars licensing of speech or the press without regard to subject matter, the twentieth-century expansion of the freedom of speech and the press leaves the impression that this freedom centers on political opinion, and this may seem to suggest that the IRB laws, which merely regulate the pursuit of scientific knowledge, are not particularly worrisome or unconstitutional. Licensing of speech or the press, however, is dangerous as to many sorts of opinion or knowledge, including scientific knowledge. Unable to forget this point, the ghost of Galileo lingers near the offices of IRBs—once again waiting for permission—and those who pause to listen can hear him whisper what all too long has been forgotten: that scientific knowledge has a political, social, and individual significance that reaches up to heights unmeasurable by any licenser, and that because the licensing of speech or the press deprives individuals of their authority to pursue this “generalizable knowledge,” it is no less dangerous than in the past.¹⁸³

A. *The Political, Social, and Individual Dangers of Licensing*

Licensing of speech or the press undermines individual authority in ways that can have political, social, and individual dangers. In different periods of human history, this range of dangers can be observed as to different sorts of opinion and knowledge, but in modern times it is especially clear as to scientific knowledge.

¹⁸³ Galileo had to get a license to print his *Dialogues*, and after having this license in effect revoked in 1633, he had to worry about how to get his new writing in print. For details, see *infra* note 188.

It has been seen that a law that requires one to get permission for the use of language, whether spoken or printed, undermines the authority of individuals and thus of the people in relation to government, and this political danger can arise from licensing of speech or the press in many fields of opinion and knowledge, including scientific knowledge. The danger reaches beyond political opinion because political opinion or knowledge cannot easily be segregated from opinion or knowledge in other fields. For example, although some individuals prefer to understand society and its politics on the basis of their religious insights, others prefer an understanding based on secular moral ideals or on scientific knowledge. Licensing therefore can threaten the authority of individuals and the people in relation to government not merely by focusing on political opinion, but also more deeply, if less immediately, by concentrating on the knowledge underlying society and its politics. Especially because scientific knowledge has contributed so much to modern society and its politics, the licensing of speech or the press in the pursuit of scientific knowledge can invert the authority of individuals and the people in their relation to government.

More generally, the application of licensing of speech or the press to scientific knowledge threatens the very success of modern society, quite apart from its politics. Like the pursuit of truth in many fields, the pursuit of scientific knowledge depends upon the authority of individuals to explore their divergent, idiosyncratic theories or generalizations, and therefore when licensing of speech or the press undermines the authority of individuals in their pursuit of scientific theories or generalizations, it weakens the sort of knowledge that has shaped modern society and has given it so much of its strength. Although no society can exist on scientific knowledge alone—or any other single sort of knowledge—modern American society is peculiarly dependent upon this “generalizable knowledge.”

In addition to these political and social dangers is a more individual danger—the peril of licensing for the individual pursuit of truth. Government is established for the preservation of individual freedom, including, perhaps most fundamentally, the freedom of individuals to discern truth as best they can. Of course, they submit to government to get its protection, and they therefore cannot claim a freedom to pursue knowledge contrary to law, which includes a wide range of after-the-fact penalties on speech and the press. Nonetheless, the First Amendment preserves their freedom from laws requiring licensing of speech or the press, and individuals can thus retain a sense of their own authority to use verbal language, spoken or printed, in the pursuit of knowledge.¹⁸⁴ This sense of personal authority, in-

¹⁸⁴ There obviously is nothing new about the assumption that individuals do not sacrifice all of their freedom to government or that the freedom they reserve includes a freedom to pursue the truth within the laws punishing injurious conduct. Two examples from 1784 can illustrate the point. Jefferson wrote:

[I]n France the emetic was once forbidden as a medicine, and the potatoe as an article of food. Government is just as infallible too when it fixes systems in physics. Galileo was sent to the In-

dependent of government, is the foundation of an individual's capacity to reach his own judgments—so that, however erroneous, they are at least his

quisition for affirming that the earth was a sphere: the government had declared it to be as flat as a trencher, and Galileo was obliged to abjure his error. This error however at length prevailed, the earth became a globe, and Descartes declared it was whirled round its axis by a vortex. The government in which he lived was wise enough to see that this was no question of civil jurisdiction, or we should all have been involved by authority in vortices. In fact, the vortices have been exploded, and the Newtonian principle of gravitation is now more firmly established, on the basis of reason, than it would be were the government to step in, and to make it an article of necessary faith. Reason and experiment have been indulged, and error has fled before them. It is error alone which needs the support of government. Truth can stand by itself.

THOMAS JEFFERSON, NOTES ON THE STATE OF VIRGINIA, in *THE LIFE AND SELECTED WRITINGS OF THOMAS JEFFERSON* 187, 275–76 (Adrienne Koch & William Peden eds., 1944) (1784).

In 1784, Richard Price more moderately observed that generalizations about truth—religious or scientific—were beyond the jurisdiction of government:

When men associate for the purpose of civil government, they do it not to defend truth, or to support formularies of faith and speculative opinions; but to defend their civil rights, and protect one another in the free exercise of their mental and corporeal powers. The interference, therefore of the civil authority in such cases is directly contrary to the end of its institution. The way in which it can best promote the interest and dignity of mankind (as far as they can be promoted by the discovery of truth) is, by encouraging them to search for truth wherever they can find it; and by protecting them in doing this against the attacks of malevolence and bigotry.

RICHARD PRICE, OBSERVATIONS ON THE AMERICAN REVOLUTION, AND THE MEANS OF MAKING IT A BENEFIT TO THE WORLD 25–26 (1784). Price wrote this in the hope that Americans would leave the pursuit of knowledge—religious or scientific—to individuals, who, being free from interference, would make “[m]any . . . discoveries” that “will give new directions to human affairs.” *Id.* at 110. More concrete legal arguments about the freedom the people reserved from government were commonplace—as when James Wilson influentially argued for ratification of the U.S. Constitution, even without a Bill of Rights, on the ground that the Constitution did not give Congress any power over speech or the press. James Wilson, Speech in State House Yard (Oct. 6, 1787), in 2 *THE DOCUMENTARY HISTORY OF THE RATIFICATION OF THE CONSTITUTION* 168 (1976). Nonetheless, Americans adopted the First Amendment to ensure that even if Congress could use its powers to regulate speech or the press, any such regulation—at least in the form of licensing—would be unconstitutional.

If the pursuit of the truth transcended distinctions among political, religious, scientific, and other subject matters—let alone between opinion and knowledge—then the religion clauses of American constitutions protected the religious aspect of this freedom and the speech and press clauses protected another aspect, which was not so narrowly confined to a single subject. The underlying point about the indivisibility of inquiry was commonplace, but Jefferson and Price took a particular interest in it because of their shared Unitarianism. Price, for example, began by considering religious doctrines and quickly expanded out to scientific doctrines, taking the deeper question to be the pursuit of any doctrine or theory, regardless of whether it focused on higher or lower things:

Anaxogoras was tried and condemned in Greece for teaching that the sun and stars were not Deities, but masses of corruptible matter. Accusations of a like kind contributed to the death of *Socrates*. . . . *Galileo* was obliged to renounce the doctrine of the motion of the earth, and suffered a year's imprisonment for having asserted it. And so lately as the year 1742, the best commentary on the first production of human genius (Newton's *Principia*) was not allowed to be printed at Rome, because it asserted this doctrine.

PRICE, *supra*, at 24–25. These doctrines were the theories or statements that the federal government calls “generalizable knowledge,” and although in religion and politics they tend to be called opinions and in science they more cautiously are called hypotheses or theories, they are the statements with which men for thousands of years have asserted and thereby tested new understandings of themselves and their circumstances.

Incidentally, Price's *Observations* not only were addressed to Americans but also were reprinted here. Indeed, the passages quoted here were selected for publication in American newspapers.

own—and although this is peculiarly essential in religion, it is also important in science and all of the other matters in which individuals seek to understand themselves and their world.

B. The New Philosophy

The dangers of licensing the pursuit of “generalizable knowledge” are evident from the history of licensing speech or the press in scientific inquiry. The pursuit of generalizable knowledge through empirical inquiry was the foundation of the new, scientific philosophy with which men created the modern world. When no longer satisfied with certitudes about their creator and his place in another world, they came to examine themselves and their place in their world, and they did this by testing hypotheses or general statements against empirical observations. They thereby transformed their society and established a new era, in which men reshaped every field of human endeavor, from medicine to politics. Yet as typified by Galileo, they soon found that their new, scientific, “generalizable knowledge” was as vulnerable to the licensing of speech and the press as any older form of knowledge, and as both Galileo and his adversaries understood, neither the new philosophy nor the licensing of it was without broader consequence. Although the sort of knowledge imperiled by licensing was changing, the danger for all that rested upon knowledge remained undiminished.

An older sort of knowledge had been pursued by Socrates in the groves of the Athenian academy. He there examined his “human subjects” through a sort of colloquy or *elenctic* inquiry designed to reveal the nature of humanity and the human good. In his study of his human subjects, Socrates often left them feeling angry or at least perturbed, but he did so because it was essential to his inquiry to provoke them into reconsidering their deepest assumptions. He thereby sometimes diminished their reputations—so effectively that even today some of his human subjects remain objects of contempt among students. The goal of the old philosophy, however—as expounded by Socrates and especially his student Plato—was to discern a truth that rose above the particulars of this world, and it was in pursuit of this higher knowledge that both the real and the Platonic Socrates troubled their human subjects.

Aristotle later turned toward a study of worldly phenomena, but rather than seek testable generalizations about human beings and their material circumstances, he discerned a natural hierarchy of creatures in a “metaphysical hierarchy.” His thought therefore, together with the rest of the old philosophy, long was popular among Christian theologians, who relied upon it to expound otherworldly truths about this world and its maker. Eventually, however, their verities were disturbed by the new philosophy.

The new philosophy and its attempt to develop testable generalizations has reshaped human life during the past five hundred years. Copernicus

and, increasingly, others, including Galileo, worried that their observations of the planets could not easily be reconciled with the Aristotelian and Ptolemaic vision of an earth-centered universe, and on the basis of growing empirical observations, the new astronomers eventually persuaded their contemporaries that the planets, including the earth, revolved around the sun. By dislodging the heavens, these astronomers encouraged others to focus their attention on the earth and its inhabitants, and in this spirit Francis Bacon boldly declared that empirical study—the testing of generalizations for error against worldly observations—would create a new age of scientific knowledge, in which scholars would no longer merely speculate about the next world, but would examine human beings and the material world in which they live. Rejecting theories ungrounded in the material realities of the physical universe, men would examine themselves and their circumstances for verifiable generalizations that could transform their lives. Bacon even foresaw how this active, empirical examination of human beings and their surroundings would allow mankind to master nature and so attain an unexpected longevity, comfort, and happiness.¹⁸⁵

A contemporary, John Donne, recognized the transformative consequences of the new empiricism in the heavens and on earth. In particular, he understood that this new philosophy was displacing medieval verities about the elements with empirical evidence of other worlds and the frangible character of this one:

And new Philosophy calls all in doubt,
The Element of fire is quite put out;
The Sun is lost, and th'earth, and no mans wit
Can well direct him where to looke for it.
And freely men confesse that this world's spent,
When in the Planets, and the Firmament
They seeke so many new; then see that this
Is crumbled out againe to his Atomies.

In breaking up the Aristotelian order of the universe, the new philosophy pulled down the old political and theological hierarchy and elevated man—to be precise, the individual:

'Tis all in peeces, all cohaerence gone;
All just supply, and all Relation:
Prince, Subject, Father, Sonne, are things forgot,
For every man alone thinkes he hath got
To be a Phoenix, and that then can bee
None of that kinde, of which he is, but hee.
This is the worlds condition now . . .¹⁸⁶

¹⁸⁵ PEREZ ZAGORIN, FRANCIS BACON 127–28 (1998).

¹⁸⁶ An Anatomy of the World: The First Anniversary (1611), in *THE COMPLETE POETRY AND SELECTED PROSE OF JOHN DONNE* 198–99 (Charles M. Coffin ed., 2001).

Such were the consequences of the new philosophy, and nowhere has it more substantially altered human life than in America. Here more than anywhere, the new, human-centered philosophy and its focus on the direct study of humanity has created a world based on empirical knowledge about men and their circumstances.

Like the old philosophy, the new one has come to be licensed, and this has meant that the licensing has had to be reoriented from God to men. It might be assumed that sixteenth- and seventeenth-century licensing only concerned political opinion, but in fact it covered speculation about the entire divine order of the universe, from the heavens to the earth. The medieval Catholic Church licensed theological manuscripts on account of their speculation concerning knowledge of God, and it eventually adapted the system for the licensing of printed books—this being the model for what became the English licensing system.¹⁸⁷ As the old philosophy at this period largely consisted of verbal speculation about God and all that was imbued with his authority, including government, the licensing of manuscripts and books sufficed to protect society from the pursuit of higher knowledge. This theologically oriented licensing, however, also had to suffice against the early pursuit of the new philosophy. The Church thus tried Galileo in 1633 and denied him further permission to print his work, not because of the implications for humanity, but because Galileo's study of the heavens had disturbing implications about God—because in moving the center of the solar system from the earth to the sun, his research shifted the center of the moral universe from God to man.¹⁸⁸

Today, licensing has been revived, but being a response to anxieties about the new philosophy and its worldly focus, it licenses scientific rather

¹⁸⁷ FREDRICK SEATON SIEBERT, *FREEDOM OF THE PRESS IN ENGLAND, 1476–1776*, at 41–63 (1952); Hamburger, *supra* note 15, at 671–72. Thus, not only in Italy but also in England, the licensing began as largely theological and then became more general—it being understood that the political, the ecclesiastical, and the academic were inextricably linked.

¹⁸⁸ A central charge against Galileo was that he had obtained a license under something like false pretenses. Although Galileo had been warned by Bellarmine not to advocate his ideas, Galileo in 1630 sought a license to print his *Dialogue*. Galileo wrote the book in such a way that he thought he could claim it did not violate Bellarmine's warning, and Galileo therefore "did not judge it necessary" to mention the warning to the licensing official. Galileo's First Deposition (Apr. 12, 1633), in *THE GALILEO AFFAIR: A DOCUMENTARY HISTORY* 261 (Maurice A. Finocchiaro trans., 1989) [hereinafter *GALILEO AFFAIR*]. The Inquisition, however, condemned him, saying that "you asked for permission to print it without explaining to those that gave you such permission that you were under the injunction of not holding, defending, or teaching such a doctrine in any way whatever." The Inquisition therefore demanded his abjuration and imprisonment and ordered the book to be "prohibited by public edict." Sentence (June 22, 1633), in *GALILEO AFFAIR*, *supra*, at 289, 291.

Religious sensibilities remain evident in the IRB licensing. Religious ethicists played an important role in the adoption of the IRB laws—not least in advising the commission that adopted the *Belmont Report*—and their heightened understanding of moral duties pervades that document. See *supra* note 148. The government, moreover, urges institutions that "[t]he nonaffiliated member of the IRB should be drawn from the local community-at-large. Ministers, teachers, attorneys, business persons, or home-makers are possible candidates." IRB GUIDEBOOK, *supra* note 49, at ch. I, pt. B.

than speculative study and seeks to protect not the dignity of God, but of men.¹⁸⁹ The licensing of the new philosophy therefore reaches deeper than the licensing of the old philosophy. Whereas the licensing of printing was largely adequate to confine the old speculation about God and the reach of his authority down to mankind, a licensing of more than the press is necessary to confine the new philosophy, which works up from empirical observations about men and their circumstances. This was the generalizable knowledge introduced by Bacon and Galileo and that seemed so disturbing to Donne, and to tame the anxieties caused by the pursuit of this sort of knowledge, the federal government has had to introduce not merely licensing of printing, but also the licensing of what is said, asked, observed, recorded, and published.

As with the old philosophy, so with the new, licensing threatens more than political opinion, for it also limits the knowledge that tends to underlie politics, society, and individual judgment. It has become commonplace to assume that the First Amendment primarily protects political opinion. Yet just as the dialectical logic of scholasticism provided a foundation for medieval politics, society, and individual inquiry, so too “generalizable knowledge” or scientific hypotheses underlie much of modern politics, society, and inquiry, and thus all the political, social, and personal developments that rest upon such knowledge remain as vulnerable to the licensing of speech and the press as what once depended upon the old philosophy. The range of political, social, and individual dangers from the licensing of the new philosophy was already becoming clear when Galileo struggled to get a license to publish his research, and today the licensing conducted by IRBs has equally broad consequences.¹⁹⁰

Thus, although the type of knowledge that dominates society has changed, the danger of regulating it through licensing of speech and the press remains undiminished. Both in recent times and in the past, the dominant type of knowledge has consisted of what could be written and said, but whereas government once licensed the political, scientific, and theological study that was expected to derive truths from the creator and his world, it now licenses scientific study of this world and those who remake

¹⁸⁹ Indeed, IRBs are sometimes justified as protecting the “dignity” of human subjects, and among the harms they are supposed to prevent are “dignitary harms.” See, e.g., Hamburger, *supra* note 6, at 325 n.129.

¹⁹⁰ For a brief summary of Galileo’s difficulties in getting a license for his *Dialogue* in 1630 and 1631, see Special Commission Report on the *Dialogue* (Sept. 1632), in GALILEO AFFAIR, *supra* note 188, at 218–19. Like modern scholars who deal with IRBs, Galileo faced repeated delays and requests for modifications, and he had to make clear “with how much humility and reverent submission I defer to the authority of superiors.” Letter from Galileo to the Tuscan Secretary of State (Mar. 7, 1631), in GALILEO AFFAIR, *supra* note 188, at 208. Yet “[i]n the meantime the work stays in a corner, and my life is wasted.” *Id.* Similarly, see Letter from Galileo to the Tuscan Secretary of State (May 3, 1631), in GALILEO AFFAIR, *supra* note 188, at 211.

it. The licensing thus has simply shifted focus from the knowledge that mattered then to the knowledge that seems to matter now.

In sum, by licensing attempts to develop “generalizable knowledge,” the federal government expressly licenses the use of language in the pursuit of modern, scientific knowledge—indeed, in its central application, to human beings—and the government thereby penalizes precisely the sort of empirical inquiry that displaced the old philosophy with the new and that refocused knowledge away from abstract speculation about men as they might be in a better world and toward the empirical study of human beings as they are in this one. The IRB laws thus target the empirical conception of knowledge that disrupts traditional verities and that continues to create the modern self, modern society, and modern politics. As Galileo’s ghost surely understands, this licensing of speech and the press is not the less dangerous because it concerns the new philosophy rather than the old.

C. Individual Authority in Pursuing Scientific Knowledge

This licensing poses such a threat to scientific knowledge and all that rests on it because it undermines individual authority in the pursuit of science. The generalizable knowledge at which the IRB laws take aim is that which, as has been seen, consists of hypotheses, theories, and other testable general statements, and especially as applied to human beings, it is the basis of the modern world—including not only its politics but also its social relations and its veneration of the individual. This knowledge has had such success, both in explaining the world and in altering it, precisely because it does not come from any central, unifying authority, but rather arises from the divergent insights and judgments of myriad individuals, each of whom explores generalizable knowledge on his own authority.

The diffused, individual authority required for the advancement of scientific knowledge is evident from the dependence of this knowledge on testable generalizations. Rather than assume that any person or government has authority to declare knowledge or its limits, the modern, scientific method aspires only to hypotheses, theories, or other generalizations, which get published so that they can be tested—that is, so that they can be questioned, challenged, and refuted. Proving error thus becomes the avenue toward a truth that always lies ahead, in wait of further attempts at generalization and further publication and testing. The success of this process of repeated experimentation and error depends on the authority of individuals to challenge old generalizations and to propose new ones, notwithstanding the views of government, a majority, or any local community, and this individual authority cannot easily survive under laws that require individuals to get permission—to submit to the authority of others—before attempting to develop their scientific generalizations.

Incidentally, this individual authority is desirable among researchers not only for the development of scientific knowledge but also as a means of

limiting research injuries. Although it cannot be expected that all researchers will accurately judge their legal and moral duties, no government or university can adequately oversee and direct individuals in all aspects of their research. It is therefore inevitable that the safety of human subjects will rest primarily on the judgment of researchers. According to Levine, “the most important reason that the record is so good and that there have been so few injuries is that most researchers are keenly aware of the potential for injury and take great care to avoid it.”¹⁹¹ In fact, scholars and students in all fields of research recite stories of how they have protected their subjects from their IRB—whether it be an anthropologist who abandoned his research because the IRB required informed consent documentation that would have gotten his subjects killed, or a neuroscientist who less prudently misinformed the IRB about the phone numbers of human subjects because the IRB had repeatedly failed to keep such numbers confidential.¹⁹² This individual responsibility—even at a high cost to the researcher—tends to rest on a deep sense of individual authority, which is bolstered by after-the-fact penalties, such as those imposed under the law of negligence. IRBs, in contrast, through their licensing, implicitly question the authority of researchers to make judgments for themselves about law or morals, and IRBs thus undermine the authority and responsibility of the very individuals who are in the best position to protect human subjects.

The danger thus is not merely the modification of over 100,000 research proposals every year, but the tendency of researchers to internalize the message that they lack the individual authority to exercise their own judgment in their pursuit of scientific knowledge. When a teacher or student seeks to learn by studying human subjects—often merely by talking with them or reading about them—he usually must first submit to the authority of the IRB, and in thus bowing to the government’s requirement that he get permission, he learns that he lacks the authority to exercise his own judgment about his pursuit of generalizable knowledge. He must defer to the IRB’s “community” pre-judgment not only about safety but also about the morality of his research, about the scientific “quality” of his method, and about “the importance of the knowledge” he eventually will publish.¹⁹³ Rather than choose what he considers a lawful, moral, effica-

¹⁹¹ LEVINE, *supra* note 59, at 26.

¹⁹² The dramatic details and source of the first story obviously cannot be identified here, and, indeed, most researchers are reluctant to allow their stories to be repeated in print, lest their IRBs prevent them from doing further research or get them fired. The details and sources of the second story can be repeated because the IRB forced it into the public realm. It is the story told by Justine Sargent in her final publication. *No End to Our Nightmare in Sight, Suicide Note Says*, MONTREAL GAZETTE, Nov. 24, 1994, at A4 (with thanks to John Mueller for drawing my attention to this story). Of course, IRBs operate under a different system of law in Canada than in the United States, but Sargent’s story at least is one that can be discussed without fear of causing further harm to the researcher.

¹⁹³ For “community” attitudes, see *supra* notes 55, 113–15 and accompanying text. For “quality” of methods, see Uniform FDA Standards for Institutional Review Boards, 43 Fed. Reg. 35,188 (Aug. 8, 1978) (regarding NIH’s requirements for IRBs); IRB GUIDEBOOK, *supra* note 49, at ch. I, pt. B; Ham-

cious scientific method, the individual learns that such judgments do not belong to him—not even in the first instance—and he thus learns that when pursuing “generalizable knowledge”—when seeking scientific generalizations—he must give up his independent, individual authority.¹⁹⁴

By undermining the authority of individuals to make their own judgments in the pursuit of scientific knowledge, the licensing puts the very success of modernity at risk. The advancement of modern science and all it has produced depends on the idiosyncratic scientific judgments of countless individuals, who enjoy not merely the freedom to make such judgments but also the sense of their own authority to do so, regardless of whether they thus depart from familiar conventions that may seem comforting to a majority or its licensors. This authority of each individual to seek generalizable knowledge in accord with his own scientific judgment has been the preeminent instrument of modernity, whether in medicine, business, the arts, morals, or politics. Accordingly, if the licensing of Socrates in his pursuit of the old philosophy would endanger individual authority and stultify the exploration of knowledge, so too does the licensing of Galileo and his intellectual heirs in their pursuit of the new philosophy.¹⁹⁵

The point, of course, is not that the United States seeks to impede modern science, but rather that the *demos*, as in the past, distrusts the unsettling inquiries made in pursuit of knowledge. The United States, being a republican system of government, is almost as responsive to this popular anxiety as the democratic system of Athens, and as in the era of Galileo and

burger, *supra* note 6, at 309–10, 346. For “the importance of the knowledge,” see 45 C.F.R. § 46.111(a)(2) (2005).

¹⁹⁴ According to one study, 25% of biomedical researchers, 38% of behavioral and social sciences researchers, and 23% of other researchers who did IRB-reviewed research felt that “[t]he review procedure is an unwarranted intrusion on an investigator’s autonomy—at least to some extent.” National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *supra* note 162, at 75. Of course, much lower percentages of IRB members thought there was an unwarranted intrusion on an investigator’s autonomy. *Id.*

As for the government funding that underlies much modern science, it was aptly said by Donald S. Fredrickson—a former Director of NIH—that “[t]he creative engines can be fueled by governments, but they cannot be ignited by them.” *The Public Governance of Science: Hearings Before the Subcomm. on Health and Scientific Research of the Sen. Comm. on Human Resources*, 95th Cong. 315, 322 (1977) (testimony of Donald S. Fredrickson).

¹⁹⁵ Although the danger of licensing in science is not clear from the opinions of the Supreme Court, it has long been evident to those who have paid attention to licensing. In his *Areopagitica*, John Milton protested that the English licensing system was “the greatest discouragement and affront, that can be offer’d to learning, and to learned men.” MILTON, *supra* note 1, at 20. As Milton was worried that some would not believe this—that they would think “these arguments of learned men[']s discouragement . . . are meer flourishes, and not real”—Milton recited how he “visited the famous *Galileo*,” who had “grown old, a pris[o]ner to the Inquisition, for thinking in Astronomy otherwise than the Franciscan and Dominican licensors thought.” On account of this “undeserved thralldom upon le[a]rning,” the scholars Milton met abroad “did nothing but bemoan the servile condition into which learning amongst them was brought.” *Id.* at 24–25. For an appreciation of Milton’s contributions, although not with the focus taken here, see Vincent Blasi, *Milton’s Areopagitica and the Modern First Amendment*, 4 IDEAS 6 (1996).

Milton, licensing seems to offer the surest protection against those who seek knowledge. IRB licensing thus combines the worst of ancient Athens and early-modern Rome—democratic fears and an authoritarian method of control—and IRBs thereby profoundly threaten the authority of individuals to pursue the knowledge that underlies modernity.

The anxiety that individuals might take scientific inquiry too far has changed little over the centuries—except that whereas science once seemed to disturb an order derived from divine ideals, it now seems to threaten an order built upon the empirical study of men. There was a time, during the Enlightenment, when it was commonplace to assume that scientific study was entirely compatible with religion, and in this spirit the American astronomer David Rittenhouse in 1775 dismissed the old fear that an astronomical discovery could be of a “dangerous tendency with respect to the interests of religion,” for “truth is always consistent with itself.” He could therefore playfully address the American Philosophical Society with a proposal to bar scientific discoveries, lest they disrupt heavenly ideals:

How far indeed the inhabitants of the other planets may resemble man, we cannot pretend to say. If like him they were created liable to fall, yet some, if not all of them, may still retain their original rectitude. We will hope they do: The thought is comfortable.—Cease Galileo to improve thy optic tube. And thou great Newton, forbear thy ardent search into the distant mysteries of nature; lest ye make unwelcome discoveries. Deprive us not of the pleasure of believing that yonder radiant orbs, are the peaceful seats of innocence and bliss. Where neither natural nor moral evil has ever yet intruded¹⁹⁶

This sort of easy reconciliation of science and religion—replete with a lighthearted admonition to Galileo—was only an interlude. In the prior century, Galileo had difficulty getting a license, lest his research interfere with comfortable thoughts about God. Today, licensing has reappeared, but this time the research that seems dangerous is that which deprives men of their comfortable thoughts about themselves.

The new philosophy and the world it established stimulate new fears almost every day—in medicine, the environment, morals, social relations, and politics—but it is profoundly dangerous for government to respond with laws licensing speech or the press, for such laws supplant the authority of individuals in their scientific inquiries.¹⁹⁷ The government thereby inverts the relation of the people to government, it deprives them of the benefits of the knowledge that continually reshapes modern society, and it undermines the capacity of individuals to pursue truth in accord with their own judgments.

¹⁹⁶ DAVID RITTENHOUSE, AN ORATION 18–19 (1775).

¹⁹⁷ One need only consider questions about stem cells, genetic testing, sexuality, and various modes of contraception and abortion to recognize the intense personal and political fears stimulated by research.

D. Socrates in America

Imagine Socrates in America. The same face, the same beard, the same inquisitive, questioning mind, but the *pallium* laid aside for scruffy tweed. This American Socrates, like his forebear, interrogates his subjects to explore his theories about the nature of human beings. In the manner of the Socrates of old, he presses his subjects with questions they find annoying, invasive, disturbing, insensitive, and embarrassing. This new Socrates, however, exposes their inadequacies in pursuit of the new philosophy—in pursuit of its empirical, generalizable knowledge and its utterly material vision of the good life. Much therefore has changed in the shift from the Athenian academy to the American. Yet even in exchanging the old philosophy for the new, Socrates would find the threat to inquiry all too familiar. Today, the inquiry that disturbs the public is empirical rather than *elenctic*, but still the academic must answer to the *demos*.

Yet whereas the original Socrates faced trial after his inquiries provoked popular anxiety, the empirically-minded American Socrates faces trial beforehand. He never even gets to ask all his questions, for prior to initiating his dialogues, he has to prepare a research proposal—with a written transcript of his questions—and submit it to the IRB, which will deny him permission until he tones down his questions in accord with its understanding of communal standards. Outside the groves of the academy, Americans are breaking all communal boundaries in what they say, print, and do, but within the academy—whether in asking about medical, political, sociological, historical, literary, religious, or other matters—the new Socrates must submit to the decision of the *demos* before he puts even a single question to his human subjects.

What do the dialogues of Socrates look like after an IRB has had its way? In the Athenian academy, the original Socrates was at least able to press his inquiries and then pay the price. Today, in the American academy, the empirically-minded Socrates must begin each dialogue by asking participants to read and sign written informed consent documents. Upon learning that they will be asked sensitive questions that might embarrass them or injure their reputation, many participants hesitate to sign, barring Socrates from even initiating the conversations. This forces Socrates to abandon several of his early dialogues. He then softens his questions in the hope that he can get permission to use less formidable consent forms. Even so, some of his milquetoast questions are removed or rewritten by the IRB to ensure that he does not provoke his subjects to think in a way the IRB considers harmful to their emotional condition. Of course, when asking his pre-approved questions, Socrates finds the dialogue rather stilted, for he is not accustomed to reducing any part of his colloquies to writing—before or after they occur. He is a man of his word, and he therefore does not depart from the script approved by the IRB, but he increasingly doubts whether he should bother with his dialogues if they must first get censored by the *demos*.

The publication of Socrates' dialogues is equally troubling, for the IRB denies him permission to reveal the names of his subjects or any other identifying information about them or those whom they mention. Indeed, before his student and successor Plato can get hold of Socrates' recordings of his dialogues to study, edit, and publish them, Plato needs additional approval from an IRB. Unfortunately, the initial IRB approval for most of Socrates' inquiries required him to destroy his data—in this case, the recordings—within three years of the conversations. Even for the recordings that survive, however, the additional approval that Plato gets from the IRB requires him to remove the portions of the dialogues that might allow a reader to identify the participants. Last but not least, to publish the dialogues in a reputable journal, Plato needs to assure the editors that they can print an imprimatur, stating that the dialogues received IRB approval.

Not unlike the jury that tried and condemned the ancient Socrates, the IRB has community representation and is chosen for its "sensitivity to . . . community attitudes."¹⁹⁸ Just as the old Socrates was tried for questioning the theological values of the Athenian state—for "denying the gods recognized by the state and introducing new divinities"—so today the new Socrates is tried for departing from the pieties of the federal government about "Justice," "Respect for Persons," and "Beneficence."¹⁹⁹

Of course, the IRB does not demand that Socrates commit suicide. At least one modern Socrates—the Canadian neurological scholar Justine Sergeant—resorted to suicide after being publicly condemned before the *demos*.²⁰⁰ A modern Socrates, however, usually has no need to terminate his life after trial, for the IRB trial occurs prior to the inquiry and simply terminates the offensive pursuit of knowledge. If, however, Socrates conducts his research and publishes it without permission, the IRB (apparently following "quality assurance" practices encouraged by the federal government) will notice the offending publication and call him to account. If it deems him "uncooperative," it can review his work more severely in the future, and it can even pressure him to resign from the academy.²⁰¹ Whereas in the era of the Athenian academy the old philosophy gave offense, in the era of the American academy the new philosophy gives offense, and therefore although Socrates finally can do his old philosophy without retribution, he can do the new philosophy only if he first submits to the government's intellectual fetters.

Stanley Milgram discovered the consequences of giving offense to the modern *demos*. The sense of outrage against him still is such that one

¹⁹⁸ 45 C.F.R. § 46.107(a) (2005). For the membership requirement, see 45 C.F.R. § 46.107(d). See also IRB GUIDEBOOK, *supra* note 49, at ch. I, pt. B.

¹⁹⁹ This language appears in a translation of Socrates' *Apology*, as quoted in Percy M. Dawson, *University Ideals and their Limitations*, 47 SCI. 547, 549 (1918).

²⁰⁰ *No End to Our Nightmare in Sight, Suicide Note Says*, *supra* note 192, at A4.

²⁰¹ See *supra* notes 59, 78.

might suppose he had electrocuted his subjects. In fact, he asked his subjects to electrocute persons pretending to be subjects, and more than sixty percent of the real subjects followed their instructions in turning up the voltage higher and higher—notwithstanding ever more anguished sounds from the persons pretending to be subjects. Milgram began his experiments in 1961, during Adolf Eichmann's trial, to understand the depths of human nature, and, being an empirically-oriented Socrates, he ended up revealing to his subjects that they were of poor character—thus causing some of them various degrees of remorse and anxiety.²⁰² Like Socrates, Milgram placed his subjects in circumstances of moral discomfort to reveal disturbing features of human nature, and although he could have employed the old philosophy without troubling the *demos*, he employed the new philosophy and was therefore condemned.²⁰³

Academic inquiry and political debate must often begin with a sense of rebellion against familiar truths, and rather than respect society's conventional sense of order, they create new conventions and different conceptions of orderliness. Arguably, therefore, a sense of freedom—a sense that one does not need prior permission—will eventually promote the interests of American society much further than even the best conceptions of social

²⁰² THOMAS BLASS, *THE MAN WHO SHOCKED THE WORLD: THE LIFE AND LEGACY OF STANLEY MILGRAM*, at ch. 5–6 (2004); Stanley Milgram, *Behavioral Study of Obedience*, 67 J. OF ABNORMAL AND SOC. PSYCH. 371, 375–76 (1963). In fact, Milgram appears to have emphasized the emotional response of his subjects for effect, and “the results of the post-experimental psychological studies . . . reported ‘no evidence of any traumatic reactions.’” Ian Parker, *Obedience*, in GRANTA 71: SHRINKS, at 101, 116 (2000). Although his studies became “a minor building block of Western thought,” the standards enforced by IRBs would “prevent the obedience studies from being repeated today.” *Id.* Similarly, it has been noted that Milgram's experiments “almost certainly” could not “be conducted in the United States today,” although “[p]erhaps more than any other empirical contributions in the history of social science, they have become part of our society's shared intellectual legacy.” BLASS, *supra*, at 281, 283. Incidentally, Milgram thought that “the ‘erection of a superstructure of control [by the federal government] on sociopsychological experimentation is a very impressive solution to a nonproblem.’” *Id.* at 281.

²⁰³ For example, he was denigrated as “the mad doctor,” and Bruno Bettelheim said that Milgram's study was “in line with the human experiments of the Nazis.” Ian Parker, *Obedience*, GRANTA, Autumn 2000, at 101, 116–17 (2000); see ARTHUR G. MILLER, *THE OBEDIENCE EXPERIMENTS: A CASE STUDY OF CONTROVERSY IN SOCIAL SCIENCE* 124 (1986). So strong was the condemnation that “it may have contributed to his premature death.” Parker, *supra* note 202, at 116.

Milgram noted that some of the criticism was “based as much on the unanticipated findings as on the method” and that if “every one of the subjects had broken off at ‘slight shock,’ or at the first sign of . . . discomfort, the results would have been pleasant, and reassuring, and who would protest?” MILLER, *supra*, at 110 (quoting Milgram). This complaint was later tested in a study by Bickman and Zarantonello, who concluded:

One may wonder if the Milgram study would have been the subject of public outrage if the results had turned out differently. These data suggest that if most of Milgram's subjects had disobeyed, his experiment would have not received as much condemnation. . . . Critics may be responding to the unflattering portrayal of human nature discovered using deceptive methodologies rather than the act of deception itself.

Id. at 111.

good or orderliness that prevail at any one moment in the nation's history. This, however, cannot be known ahead of time, and therefore the First Amendment's rejection of licensing, like so much of American freedom, is a sort of wager on human nature—a calculated gamble on the capacity of Americans to make better use of their freedom than the experience of the rest of the world has given them reason to think possible. Perhaps the gamble on individual authority is mistaken, but this fragmented authority is the very foundation of the knowledge that has created modern America—its politics, its society, and its individualistic people. Accordingly, although the risks of leaving Socrates unlicensed may sometimes seem dangerously unknown, the risks of requiring him to get permission before he even begins his inquiry are all too clear.

CONCLUSION

By now it should be evident that the IRB laws regulate research by imposing licensing on speech and the press. These laws require individuals, on account of their desire for generalizable knowledge, to get permission before pursuing such knowledge—indeed, to get permission before merely observing, asking, speaking, writing, printing, recording, keeping information, sharing information, or otherwise publishing. These licensing laws thus violate the First Amendment, and although licensing has lost its prominence in First Amendment doctrine, the danger to individual authority and the consequences for individuals, society, and politics reveal that the licensing of speech or the press remains a profound threat to freedom.

It is shocking almost beyond belief that academics are prohibited from doing without prior permission what other Americans can do without concern, let alone permission. It is shocking that they are penalized merely because they belong to an inquisitive and publishing class and because they have the curiosity to seek generalizable knowledge—in other words, not for any discernable, legally punishable injury that already has occurred, but rather for being eggheads, for having curiosity, for inquiring with intent to learn, in particular for seeking the knowledge that underlies modernity. It is shocking that they are cordoned off from the rest of society and not allowed out of their intellectual confines, unless on a leash held by community licensors on behalf of the federal government.

Of course, this is not to say that the Constitution stands in the way of laws penalizing injury, including such injury as occurs in research. If Socrates or Milgram actually causes harm of a sort punishable when done by other types of Americans, he is vulnerable to a legal remedy for the actual harm. Yet neither Socrates nor Milgram can be subject to licensing or other constraints on speech or the press on account of his being an academic—on account of his being of the class that congregates in universities and other research institutions. Nor can such persons be singled out for licensing because they are curious about their fellow men and wish to study them by

asking questions and engaging in conduct that is otherwise entirely lawful. To be a member of the class *academicus* or to engage in the systematic pursuit of generalizable knowledge is not a risk, let alone an injury, and even if there were a greater risk than from the rest of population or from conduct done without scientific curiosity, the risk is not of the sort that can safely be left to the cognizance of law. Although the pursuit of generalizable knowledge by academics may appear harmful in the anxious imagination of the *demos*, it still is protected by the Constitution from laws requiring the licensing of speech or the press.

Government could just as well impose licensing on scholars who engage in *elenctic* dialogue about the nature of man, for this too puts human subjects at risk. If the licensing of Socratic inquiry or those who pursue it would violate the First Amendment, so too does the licensing of the pursuit of generalizable knowledge through the study of human subjects.

The IRB laws can be no more constitutional than NRB laws—the hypothetical laws establishing Newspaper Review Boards. A newspaper reporter can question Klansmen, he can even join the Klan to observe their prejudices all the better, and although he can publish all sorts of personal details about them, he cannot be subjected to licensing on account of his being a reporter or on account of his desire for knowledge that can be stated in verbal language—whether the knowledge is particularizable, generalizable, or publishable. Before the reporter does his research, it cannot be known whether his inquiry will do any injury, and even afterward, if his publication causes harm to a Klansman, the reporter cannot be punished, except under general laws. Perhaps in some sense researchers as a class, like reporters, are dangerous, and perhaps their curiosity carries perils, but they cannot constitutionally be constrained by law, especially not by licensing laws, on account of their desire for generalizable knowledge or their membership in an inquisitive class.

Ultimately, the problem is not so much the IRB laws as the doctrines of the Supreme Court. The doctrines that the Court developed while expanding the freedom of speech and the press may have been useful to define and thus delimit the periphery, but they have cut deeply into the core, and this has emboldened the government to impose licensing and has left academics and students without the confidence to object. In particular, the Court's doctrines have impressed Americans with the debilitating belief that government interests can overcome any part of the freedom of speech and the press and that in any case the government can spend its way around the freedom. The Court's doctrines have thereby given legitimacy to what the Constitution once clearly forbade, and thus rather than preserve liberty, the Court has actually subverted it.

The result is an almost surreal contrast between the justices' conception of their doctrines and the grim reality.²⁰⁴ The justices have repeatedly

²⁰⁴ See also Hamburger, *supra* note 6, at 277–81, 351–54.

revealed their belief that their doctrines protect freedom of expression in the academy. For example, they talk about the importance of freedom of speech and the press “particularly in the academic community” and say that “academic freedom” is “a special concern of the First Amendment.”²⁰⁵ The justices in such cases sound as if they are endorsing a freedom within the academy that rises above the freedom enjoyed outside. In reality, however, the Court’s doctrines have legitimized the imposition of seventeenth-century style licensing on academics and students and have thus deprived them of a freedom that other Americans exercise every day without impediment. The Court’s doctrines, in fact, have left academics so uncertain of their rights that for over three decades they have not challenged the licensing laws.²⁰⁶ In these circumstances, what is needed from the Court is not a special right of research or any other academic privilege, but rather merely a clear acknowledgment of the old-fashioned First Amendment freedom from licensing.

²⁰⁵ *Keyishian v. Board of Regents of Univ. of State of N.Y.*, 385 U.S. 589, 603 (1967); *Sweezy v. New Hampshire*, 354 U.S. 234, 245 (1957).

²⁰⁶ For the fearfulness of academics, see *supra* note 58 and *Hamburger*, *supra* note 6, at 304–05, 352–54. The effect of Supreme Court doctrine in undermining opposition to the licensing was candidly acknowledged by a lawyer who had been a Special Consultant to the Commission that drafted the *Belmont Report*. He observed about the government’s use of conditions to obtain IRBs: “Neither scientists nor institutions have challenged in court the power of Congress to impose such conditions, perhaps because the Supreme Court, if ever faced with the question, is likely to construe Congress’s conditional spending power broadly and to approve such conditions.” John A. Robertson, *The Social Scientist’s Right to Research: A Constitutional Analysis*, in *ETHICAL ISSUES IN SOCIAL SCIENCE RESEARCH* 361 (Tom L. Beauchamp et al. eds., 1982).